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First Interim Report to Congress

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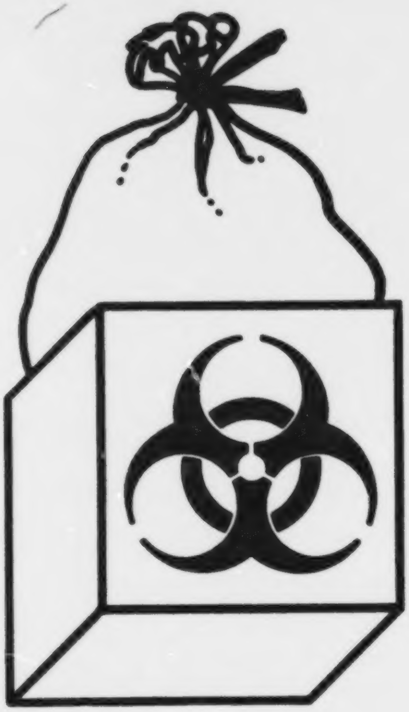

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EXECUTIVE SUMMARY

Under Subtitle J of the Resource Conservation and Recovery Act (RCRA), EPA is to report to Congress on several aspects of medical waste management and the demonstration program for tracking medical wastes. This report is the first in a series of three reports which are required by, and address the topics specified in, RCRA Section 11008(a).

Medical wastes that are subject to the demonstration program regulations are generated primarily by hospitals, and comprise approximately 0.3 percent (by weight) of the municipal solid waste stream. Wastes from home health care, which are not "medical wastes" under the definition in RCRA 1004(40), are likely to contain a significant number of syringes--one of the medical items of concern to Congress when it enacted the Medical Waste Tracking Act of 1988 (MWTA).

The health and environmental threat posed by medical waste or its incineration is a complex question. Chapter 2 outlines EPA's planned approach to conducting this assessment, by responding to the Congressional mandate to evaluate health hazards posed by routine management of medical waste. The following topics are addressed in Chapter 2:

- coordination with the Agency for Toxic Substances and Disease Registry (ATSDR)
- definitions and terms
- scope of the health hazard assessment
- general approach to evaluating present and potential health hazards from exposure to medical waste

- evaluation of health hazards posed by incineration of medical waste
- evaluation of health hazards posed by the landfilling of medical waste
- evaluation of the health hazards posed by the disposal of medical waste in sewage systems
- data gaps and research needs

The regulations which implement the two-year demonstration program are estimated to have a cost of $24 million (undiscounted); a very preliminary estimate of loss of value in three states (Connecticut, New York, and New Jersey) due to mismanaged medical wastes is in the range of $30 million. This does not mean, however, that the regulations will result in $30 million in savings. These numbers are EPA's best estimates, but they are based on a number of assumptions which are explained in more detail in Chapter 3.

In assessing the "success" of the demonstration program, EPA has defined the program's objective as ensuring that the wastes subject to the regulations are delivered to treatment or disposal facilities with a minimum of exposure to waste management workers and the public. EPA intends to evaluate the program using the criteria of state participation, compliance with the regulations, technical adequacy of the regulations, and the regulations' potential effects on recreational/occupational injuries and disease. In addition, EPA intends to evaluate the regulations' effects on beach washups and beach closings (although some washup items may be outside the scope of the MWTA), and on treatment and disposal practices. EPA is also preparing to collect information to determine the appropriateness of penalties imposed in Subtitle J enforcement actions.

Several states have enacted laws and regulatory programs, in response to the public's concerns over the AIDS epidemic, to address medical waste management; although not all of the state programs EPA is aware of require tracking, they typically require certain packaging and labeling techniques and treatment before land disposal. As part of an evaluation of existing state and local requirements, EPA plans to assess the appropriateness of these state requirements and the Subtitle C requirements to monitor and control medical waste.

Current medical waste management practices range from handling the waste as nonhazardous municipal solid waste, to strict segregation, packaging, labeling, and tracking (using paper manifests) imposed either by state requirements or through private agreement by transporters or disposal facilities. Common treatment techniques include steam sterilization and incineration. Certain medical wastes are commonly stored in refrigerators, while others are typically stored indoors or outdoors in various receptacles or containers. A number of recycling and reuse techniques are also used.

This report outlines in more detail the topics mentioned above, and explains EPA's planned activities to address these topics.

INTRODUCTION

In response to increased public concern about improperly managed medical wastes, the Medical Waste Tracking Act of 1988 (MWTA) was enacted. Through the MWTA, Congress amended the Resource Conservation and Recovery Act (RCRA) to add a new Subtitle J, which establishes a two-year demonstration program for tracking medical waste. Under Subtitle J, EPA must establish tracking and management standards for certain medical wastes. These standards apply to medical wastes generated in certain states. The MWTA also requires EPA to submit a series of reports to Congress on a number of topics related to medical waste.

Section 11002 of RCRA required EPA to promulgate regulations by May 1, 1989, listing the types of medical wastes required to be tracked in the demonstration program. Section 11003 required EPA to promulgate regulations by May 1, 1989, for segregation, packaging, labeling, and tracking those designated medical wastes. EPA met these statutory requirements by issuing regulations on March 24, 1989 (54 FR 12326). The regulations, found at 40 CFR Part 259, list the medical wastes required to be tracked. These wastes are a subset of all medical waste, and are defined as "regulated medical waste" at 40 CFR 259.30. In addition, the regulations set up the segregation, packaging, labeling, and tracking requirements authorized by RCRA Section 11003, and a requirement for generators who incinerate medical waste on-site to report to EPA.

Following publication of the regulations, several states that were designated to participate in the program elected to "opt out," while others petitioned EPA to be included in the program. RCRA Section 11001 set up this "opt out" and "petition in" procedure to allow the states' governors to determine whether they wanted to participate in a program that is not nationwide in scope. As a result of the states' actions, five states (Connecticut, New Jersey, New York, Puerto Rico, and Rhode Island) are participants in the demonstration program.

The demonstration program is of limited duration; for Connecticut, New Jersey, and New York, the program went into effect June 22, 1989. The other states were given 30 days longer to prepare their respective regulated communities for compliance, and to enable the states to coordinate their implementation activities. The program will expire in all States on June 22, 1991.

This report fulfills part of the requirement of RCRA Section 11008(b), which requires EPA to prepare interim reports containing the information on several medical waste topics available at the time of submission. This report is structured according to the topics outlined in Section 11008(a)(1) through (12). Chapter 1 addresses the information required by Section 11008(a)(1); Chapter 2 addresses Section 11008(a)(2), etc. To the extent that information items overlap, the chapters explain where the required information is found. Generally, the information presented in this first interim report reflects EPA's planned information-gathering activities; to the extent that data re available, they are included here. Chapters 4 and 9 are noteworthy in that they present EPA's criteria for determining the success of the demonstration program, outline available tracking methods, and assess the appropriateness of federal hazardous waste requirements and state/local requirements as nationwide medical waste controls.

Certain terms are used in a different manner in the statute than they are used in the regulations or in this report; where needed, these terms have been defined specifically for each chapter. For instance, the term "medical waste" in RCRA Section 1004(40) is more inclusive than the medical waste types listed in Section 11002(a). In some chapters, the broadly defined term of Section 1004(40) is used. In others, the medical waste types in Section 11002 or in 40 CFR 259.30 are the wastes that are discussed. Where possible, the term "regulated medical waste" is used to refer to the medical waste items listed in 40 CFR 259.30.

CHAPTER 1

CHARACTERIZATION OF MEDICAL WASTE

1.1 Introduction and Overview

Section 11008(a)(1) of RCRA requires information on "the types, number, and size of generators of medical waste (including small quantity generators) in the United States, the types and amounts of medical waste generated, and the on-site and off-site methods currently used to handle, store, transport, treat, and dispose of the medical waste, including the extent to which such waste is disposed of in sewer systems." The on-site and off-site methods currently used to manage medical waste are addressed in Chapters 5 through 7. This chapter presents results of EPA's efforts to date in characterizing the types, numbers, and size of generators, and types and amounts of regulated medical waste generated in the United States based on currently available information. It also explains the Agency's long-term program to more fully characterize the generation and management of regulated medical waste through reporting requirements in the medical waste tracking rule.

The waste characterization presented in this report is based on currently available information and, when such information is not available, on EPA's best estimates. Therefore, estimates presented in subsequent sections should be considered preliminary in nature. Subsequent reports will discuss the results of EPA's longer-term efforts, which will be based on data submitted directly by transporters and certain generators. Once submitted, these data will allow EPA to characterize with greater certainty the sources, amounts, and types of regulated medical waste generated, and the transport and management of regulated medical waste. In future reports to Congress, the Agency will also attempt to further characterize the generation and management of medical waste.

Section 1.2 presents a summary of estimates of the types and numbers of medical waste generators, and amounts of medical waste generated by generator type, as well as a brief description of the methodology used to develop the waste quantity estimates. Section 1.3 describes how the information reporting requirements in 40 CFR Part 259 will be used to characterize the generation and management of regulated medical waste.

1.2 Medical Waste Generation

Methodology

Briefly described, the approach used to characterize the generation of medical waste involved first categorizing the universe of generators by industry or field of practice, and by consulting trade associations, the U.S. Department of Health and Human Services (HHS), and the U.S. Department of Commerce for data on the population of each generator type. The quantities and types of regulated medical waste generated were then estimated for each generator type.

The estimates of waste types and quantities rely on data from a number of sources, including published literature, preliminary results of a survey of generators in New York and New Jersey, approximately 50 site visits to facilities generating or handling medical waste, and telephone interviews with industry. Because generators in the past have generally not maintained records of the amounts or types of medical waste they produce, relatively little quantitative information is currently available regarding waste generation for many generator types. This is especially so with smaller generators such as physicians, dentists, veterinarians, and others. For these reasons, it was often necessary to make reasonable "best estimates" of waste generation rates, based on knowledge of the generator types and their respective waste streams. For similar reasons, determining the types (and respective amounts) of medical waste generated has to date proved to be problematic.

Summary of Preliminary Results

Each year approximately 500,000 tons of regulated medical waste are produced in the United States by about 375,000 generators. As a point of reference, about 158 million tons of municipal solid waste are generated annually.[1] The vast majority of the regulated medical waste (about 77 percent) is generated by hospitals, which comprise less than 2 percent of the total number of generators. The remainder is produced by a large, diverse group of generators from several generator types, including laboratories, physicians' offices, veterinarians, etc. The majority of these generators produce relatively small quantities (less than 50 pounds per month) of regulated medical waste.

A summary of the types and numbers of medical waste generators and the approximate quantity of regulated medical waste generated by each type in the United States is presented in Table 1-1.

As can be seen in Table 1-1, there are large variations in the quantities of regulated medical waste generated by facilities of different types. Not apparent from Table 1-1, however, are results that indicate that there is a tremendous range in the quantity of medical waste produced by facilities within each generator type. While much of this variability can be attributed to differences in facility size, specialty, or types of services offered (e.g., number of beds in a hospital; number or types of doctors sharing an office), part of the variability is due to differences in waste management practices at individual facilities.[3,5,7] Thus, estimates of quantities of regulated medical waste generated per month per facility for each generator type, from Table 1-1, should be interpreted carefully, considering all the variables involved.

The differences in waste management practices between facilities of the same "type" arise for several reasons. First, facilities have differing opinions on which wastes should be considered "infectious," and therefore managed more carefully than ordinary trash. Medical waste may or may not be infectious in nature. To evaluate and define the infectiousness of medical waste requires knowledge of the type of pathogens present, the quantities of those pathogens, potential modes of disease transmission and information on the susceptible host populations. All of these factors can affect the facility's decision regarding

TABLE 1-1

Sources and Quantities of Regulated Medical Waste Generated

	Generator Type	Number of Generators	RMW Generated All Facilities (Tons/Year)	RMW Generated Per Facility (lbs/month)	Reference* Number
1.	Hospitals	7,100	359,000	8,400	2,3
2.	Laboratories	4,300	15,400	600	4,5
3.	Clinics	15,500	16,700	180	6,5,7
4.	Physicians' Offices	180,000	26,400	24	8,9,5,7
5.	Dentists' Offices	98,400	7,600	13	8,10,5
6.	Veterinarians	38,000	4,600	20	11,5,12
7.	Long-Term Health Care Facilities	12,700	29,600	390	4,5
8.	Free-Standing Blood Banks	900	2,400	440	13,14,7
9.	Funeral Homes	20,400	3,900	32	15,5
10.	Others	**			
	Total	377,300	465,600		

* An explanation of how the quantity estimates were derived, and a description of assumptions made, are included in a memo to the docket for the EPA interim final rules published March 24, 1989."

** This generator type includes health units in industry, schools, correctional facilities, fire and rescue services, and others. EPA is currently investigating the number of generators in this category (see text for further discussion).

the wastestreams it handles as "infectious." [See Chapter 2 for additional discussion of the factors necessary for disease transmission.] Second, facilities have differing incremental costs for disposal of "potentially infectious" waste, leading to differences in the effort taken to segregate wastes. For example, at facilities with low incremental waste disposal costs (e.g., those with on-site incinerators), there is little incentive to minimize the amount of "infectious" waste generated through careful segregation.

It has also been observed that the types of waste considered potentially infectious for purposes of waste management at hospitals and other health care facilities are generally fairly conservative when compared to the minimum requirements (i.e., waste classes 1-7) of the demonstration program.[3,5,7] In fact, the results of a recent nationwide survey of waste management practices at hospitals[3] found that most of the hospitals surveyed consider the following wastestreams infectious: microbiological wastes (92% of responding hospitals), pathological wastes (94%), human blood and blood products (91%), sharps (98%), contaminated animal carcasses, body parts, and bedding (84%), and communicable disease isolation wastes (98%), surgical wastes (84%), dialysis unit wastes (81%), contaminated equipment (68%), and miscellaneous laboratory wastes (85%). The latter four, waste types, are not regulated as a class under the EPA regulations (although some of these wastes may be regulated under one or more of the other classes).

Thus, the total amount of waste estimated in Table 1-1 (most of which is accounted for by hospitals) reflects these conservative waste management practices, and is likely greater than an amount that would correspond to a strict reading of the definition of regulated waste in the Part 259 regulations. Not included in the quantity estimates are ordinary garbage generated in health care settings, or home health care wastes (e.g., syringes used in the home). Available information on home health care wastes is presented in Chapter 11.

Determining the number of generators for certain generator types (e.g., physician's, dentist's, and veterinarian's offices, blood banks) has proved to be problematic for several reasons. First, the extent to which certain generators are actually producing medical waste is not well known. A certain fraction of doctors, for instance, may be retired, or may be teaching, or may be in a specialty that does not generate regulated medical waste. Second, the extent to which doctors or other health care providers practice in groups is not well documented. Therefore, the estimates of numbers of generators probably carry a large degree of uncertainty and most accurately reflect the potential, rather than actual, numbers of generators.

There are also many other types of facilities that may generate regulated medical waste that are not included in generator types listed in Table 1-1. These include health care units at schools, universities, office buildings, factories, and prisons, zoos, emergency service providers (e.g., fire, police, rescue), and others. Many of these facilities have traditionally not been thought of as medical waste generators, and in fact, EPA has no information on the number actually generating regulated medical waste. It is clear, however, that the potential number of generators in this category is very large--by some accounts, as many as 200,000." EPA intends to evaluate the size of this category using information submitted in the transporter semi-annual reports (see Section 1.3 below), and will report its findings in subsequent reports to Congress.

1.3 Medical Waste Data Collection Activities

As previously discussed, EPA is not confident that existing estimates of the sources or amounts of medical waste generated are accurate. The Agency has taken steps to address this problem by incorporating three information reporting requirements into 40 CFR Part 259. The first requires transporters to notify EPA of their intent to transport regulated medical waste. The second requires these transporters to submit reports semi-annually during the demonstration program, summarizing the source and disposition of the regulated medical waste they transported. The last requires generators who incinerate medical waste on-site to report to EPA on the amounts of waste incinerated, the type of incinerator used, and its operation. The information provided in these reports will help the Agency characterize the generation, transportation, and disposal of medical waste quantitatively. Each of these requirements is discussed further below.

Transporter Notification

The medical waste tracking rule [see 40 CFR 259.72] specifies that each transporter who handles regulated medical waste that is generated in a Covered State must notify EPA for each Covered State in which the waste was generated. EPA then issues one identification number to each transporter for that transporter's operations in all Covered States.

There are several important benefits of this notification with respect to information collection. At the beginning of the demonstration program, EPA established a list of all transporters who have notified EPA of their operations for each Covered State. This information will form a valuable baseline from which changes in the universe of haulers can be measured. EPA and the States can also use this information in monitoring the program's implementation and can ensure that generators utilize transporters who are aware of and understand the regulations.

Results

By the effective date of the demonstration program, 161 transporters had notified EPA of their intention to haul regulated medical wastes originating in Covered States.[7] The number of companies notifying and the number of facilities, or terminals, for each Covered State are summarized in Table 1-2. For each Covered State, the number of notifications, the number of companies transporting medical waste that are located in the State, and the number of facilities or terminals located in the State may differ because some companies may operate several terminals in a single State, and other companies may service several Covered States from a single facility. Furthermore, because the program is new, some transporters may be late in notifying, and others may notify but not actually haul medical waste. Thus, these results should also be considered preliminary.

TABLE 1-2
Transporter Notification Information
(as of August 30, 1989)

Covered State	Number of Transporters Notifying for Covered State[1]	Number of Facilities Located in Covered State[2]
Connecticut	42	8
New Jersey	54	25
New York	118	84
Puerto Rico	3	3
Rhode Island	29	3
Total	246	123

Total number of companies transporting Regulated Medical Waste that is generated in Covered States: 161

SOURCE: Reference 17

[1] Number of transporters that have notified of their intent to transport regulated medical waste generated in the Covered State.

[2] Number of facilities or terminals operated by transporters that are located in the Covered State.

Transporter Periodic Reports

Under 40 CFR 259.78, transporters who haul regulated medical waste that was generated in a Covered State must report to EPA every 6 months. The reports must summarize the quantities of "treated" and "untreated" regulated medical waste accepted, and the generator type (e.g., hospital, laboratory, clinic). Methods of medical waste treatment are discussed in Chapter 6.

Transporters also must report on the amounts of regulated medical waste delivered to a treatment or disposal facility, or to another transporter. This information is also broken down into the "treated" or "untreated" categories specified in the regulations. In addition to being useful in outreach and enforcement activities, the information contained in these reports will allow EPA to characterize quantitatively the waste's generation, off-site transportation, and disposal patterns.

Data collected from the demonstration states may not be representative of the entire United States, but should provide valuable information. The information will enable EPA to report on the following:

- **The numbers and types of generators entering regulated medical waste into the tracking system, by State, and for all Covered States.**
- **The quantity of regulated medical waste entering the tracking system, broken down by "treated" or "untreated" categories, for each generator type.**
- **The numbers and types (e.g., landfill, incinerator, etc.) of facilities that dispose of or treat regulated medical waste by State, and for all Covered States.**
- **The quantity of "treated" and "untreated" regulated medical waste managed at each facility type.**

- The names and numbers of transporters handling regulated medical waste, by State, and for all Covered States.
- The quantity of "treated" and "untreated" regulated medical waste handled by each transporter.
- Changes in the numbers and types of handlers (e.g., generators, transporters, disposers) in the tracking system, and changes in amounts of regulated medical waste entering the tracking system during the demonstration program.
- Changes in off-site treatment practices during the demonstration program.
- The extent to which generators import or export Regulated Medical Waste, outside of the Covered States that is generated in Covered States.

On-Site Incinerators

Finally, 40 CFR 259.62 requires generators who incinerate regulated medical waste on-site to prepare and submit two reports; the first report covers the first six months of the demonstration program, while the second covers the thirteenth through the eighteenth months. These reports summarize information about the type of incinerator used, its operation, and the amount of waste incinerated. The report also must contain information on amounts of waste received from sources outside the facility, such as private physicians or small group practices. This information will be used to determine the amount of waste that is incinerated on-site, and hence not summarized by transporters in periodic reports.

Because on-site incinerator operators are required to submit two reports, EPA will assess changes in incineration practices attributable to the demonstration program.

In summary, the various information collection requirements of the demonstration program--the transporter notification, the transporter periodic reports, and the on-site incinerator reports--will enable EPA to develop a more complete picture of the medical waste management system. Future MWTA reports will contain summaries of regulated medical waste sources and amounts, on-site incineration practices, treatment practices, and transportation and disposal patterns. More detailed information concerning the Agency's plans to test incinerators is provided in Chapter 2.

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CHAPTER 2

HEALTH HAZARD ASSESSMENT

2.1 Background

Within the past few years, Congress and the general public have expressed increased concerns about possible disease transmission from exposure to medical waste. This heightened public awareness may be principally attributable to the growing concern with possible transmission of the Human Immunodeficiency Virus that is associated with the development of the Acquired Immunodeficiency Syndrome (AIDS), and perhaps to a lesser extent to the increased use of disposable material and equipment. Recent media reports of medical waste washups on our nation's beaches coupled with incidents of children playing in dumpsters containing needles and blood vials served as a catalyst for public demands and Congressional mandates for regulations to prevent the recurrence of such incidents.

Many experts and health care professionals have expressed opinions that any health hazards posed by medical waste are occupational and that actual threats to the general public are unlikely, even when such wastes are mismanaged or improperly disposed. They consider the issue to be a perceived threat of disease from exposure to medical waste, particularly that which may have been in contact with blood contaminated with the AIDS virus or other blood borne pathogens, as well as the unappealing aesthetics of identifiable medical waste. This position was stated by a significant number of persons who commented on the

June 2, 1988, Notice of Data Availability on issues pertaining to infectious waste (see 53 FR 20140), and was reiterated by participants at the EPA Medical Waste Meeting in Annapolis, MD (November 1988). Comments on the EPA "Draft Manual for Infectious Waste Management," (September, 1982) and the EPA Guide for Infectious Waste Management also reflect this position. [These comments are available in the RCRA docket.] Some members of Congress expressed a similar opinion in the legislative history to the Medical Waste Tracking Act of 1988 by stating that "hazards presented may be occupational rather than environmental. . . ."; but were also concerned that mishandled infectious waste could pose a threat in the community" (134 Cong. Rec. H9537).

While EPA believes that some medical waste, such as intravenous bags, poses only aesthetic concerns, the Agency also believes that other medical waste, such as cultures and stocks of infectious agents and associated biologicals, may contain pathogens in concentrations sufficient to cause disease in susceptible individuals. For those wastes containing pathogens, however, infection potential and disease transmission (discussed later in this chapter) are complex mechanisms which involve the interaction of multiple factors. The mere presence of pathogens in sufficient quantities to cause disease does not necessarily pose a hazard; a mechanism for transmission of these organisms to a susceptible host must also exist.

Determining the potential health hazards of improper management of medical waste remains one of the most complex and critical issues requiring resolution. The key question is which components of the medical waste stream pose true health hazards and, therefore, require some type of regulatory control. Congress recognized the importance of answering this question to ensure that such wastes are regulated or tracked under Subtitle J of RCRA and to provide information needed to determine if national regulations might prove useful in controlling these wastes. Thus, section 11008(a)(2) of the Medical Waste Tracking Act of 1988 requires EPA, among other things, to assess "the present and potential threat to human health or the environment from medical waste or the incineration thereof . . . " The legislative history provides some insight into the intended purpose of this assessment; suggesting that EPA should provide information on

> "...The type or category of medical waste that needs to be tracked, or whether we should just require the tracking of infectious wastes" (134 Cong. Rec. H9537).

In responding to the Congressional mandate to evaluate health hazards posed by routine management and mismanagement of medical waste, this chapter outlines EPA's proposed approach to performing this task. The following topics are addressed:

- coordination with the Agency for Toxic Substances and Disease Registry (ATSDR)
- definitions and terms
- scope of the health hazard assessment
- general approach to evaluating present and potential health hazards from exposure to medical waste

- evaluation of health hazards posed by incineration of medical waste
- evaluation of health hazards posed by the landfilling of medical waste
- evaluation of the health hazards posed by the disposal of medical waste in sewage systems
- data gaps and research needs

A subsequent interim report (due June 22, 1990) will address data gathered and analyzed by the time of submission. The final report to Congress will present findings, options, and recommendations for future research needs. EPA expects that data from the health hazard assessment, when coupled with data on current medical waste management practices, will provide a basis for determining whether any types of medical waste require controls and whether controls over certain types or categories of medical waste which may pose a hazard to the general public can reduce or eliminate that hazard.

2.2 Coordination with the Agency for Toxic Substances and Disease Registry (ATSDR)

Pursuant to §11009 of Subtitle J, ATSDR is required to report to Congress on the health effects of medical waste. ATSDR's report will include the following:

> "1) A description of the potential for infection or injury from the segregation, handling, storage, treatment, or disposal of medical waste.
>
> 2) An estimate of the number of people injured or infected annually by sharps, and the nature and seriousness of those injuries or infections.

> 3) An estimate of the number of people infected annually by other means related to waste segregation, handling, storage, treatment, or disposal, and the nature and seriousness of those infections.
>
> 4) For diseases possibly spread by medical waste, including AIDS and hepatitis B, an estimate of what percentage of the total number of cases nationally may be traceable to medical waste."

The ATSDR report will focus on existing epidemiological data related to the transmission of disease or injury from medical waste handling, storage, treatment, or disposal of medical waste. The targeted universe of generators includes hospitals, clinics, doctors (e.g., health maintenance organizations) and dentist offices, medical laboratories, veterinary offices and clinics, biomedical research and manufacturing facilities, funeral homes, other facilities covered under the medical waste definition, and in-home health care. Injury rates were derived from scientific literature and surveys conducted by State Health Departments and the waste hauling industry. The information will include total study population, rate of injury or infection, and methodology for collecting data and determining injury or infection rate.

EPA will coordinate with ATSDR to avoid duplication of effort. As described earlier, the EPA study will focus on identifying and quantitating classes of infectious agents expected to be present in medical waste, possible routes of transmission and associated morbidity rates from exposure to these pathogens. The Agency will attempt to incorporate ATSDR epidemiological data as it becomes available into its health hazard assessment to assist in evaluating the likelihood of disease transmission.

2.3 Definitions

In any discussion of medical waste issues, including health hazards posed by these wastes, it is imperative there be an understanding of technical terms not commonly used or understood by the general public. For example, in describing the ability of a microorganism to cause disease, one must understand terms such as virulence, invasiveness, pathogen(ic), infective dose, etc. Therefore, to mitigate confusion and facilitate understanding of complex technical terms, each interim report to Congress will include definitions of terms used in the respective report. The final report will include a comprehensive glossary of terms. The Agency will consult with experts from professional trade associations and academia to ensure that the definitions are as accurate as possible.

The following terms are used in this report:

Biologicals - preparations made from organisms or from products of their metabolism, intended for use in diagnosing immunizing or treating humans or animals, or in research pertaining thereto.

Disease - (in the true sense of the term) an interruption, cessation, or disorder of body functions, systems, or organs. (A disease, e.g., a genetic disorder may manifest itself without the involvement of a microorganism.

Infection - the entry and development or multiplication of an infectious agent in the body of man or animals. Infection is not synonymous with infectious disease; the result may be inapparent. The presence of living infectious agents on exterior surfaces of the body, or upon articles of apparel or soiled articles, is not infection, but contamination of such surfaces and articles. In addition, it should be pointed out that antibody production, i.e. seroconversion, does not necessarily mean that "infection" has occurred.

Infectious agent - any microorganism that is capable of producing infection or disease and may adversely impact human health.

Medical waste - any solid waste which is generated in the diagnosis, treatment (e.g., provision of medical services), or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals. The term does not include any hazardous waste identified or listed under Part 261 or any household waste as defined in Section 261.4(b)(1).

Morbidity - disease state.

Mortality - death state.

Pathogen - any microorganism capable of causing disease.

Pathogenicity - the capability of an infectious agent to cause disease in a susceptible host.

Virulence - the disease-evoking power of a microorganism in a given host.

2.4 Scope of Health Hazard Assessment

EPA (Office of Solid Waste) has begun a search of medical and scientific journals, Agency files, and other information sources to gather data in support of the medical waste health hazard assessment. The primary focus of the health hazard assessment will be on the disease-causing potential of medical wastes through qualitative evaluations of pathogenicity and exposure potential. While the Agency will address the feasibility of performing a quantitative risk assessment for disease potential, a preliminary review of the literature indicates that a meaningful quantitative risk assessment may not be feasible due to observed gaps in areas imperative to the performance of a quantitative risk assessment, specifically dose-response and exposure data. Therefore, the Agency will explore an alternative means for expressing potential disease-causing hazards to human health (possibly through a comparative health hazard assessment). The health hazard assessment will address categories of medical waste as defined in the statute which are as follows:

"(1) Cultures and stocks of infectious agents and associated biologicals, including cultures from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures.

2) Pathological wastes, including tissues, organs, and body parts that are removed during surgery or autopsy.

3) Waste human blood and products of blood, including serum, plasma, and other blood components.

4) Sharps that have been used in patient care or in medical, research, or industrial laboratories, including hypodermic needles, syringes, pasteur pipettes, broken glass, and scalpel blades.

5) Contaminated animal carcasses, body parts, and bedding of animals that were exposed to infectious agents during research, production of biologicals, or testing of pharmaceuticals.

6) Wastes from surgery or autopsy that were in contact with infectious agents, including soiled dressings, sponges, drapes, lavage tubes, drainage sets, underpads, and surgical gloves.

7) Laboratory wastes from medical, pathological, pharmaceutical, or other research, commercial, or industrial laboratories that were in contact with infectious agents, including slides and cover slips, disposable gloves, laboratory coats, and aprons.

8) Dialysis wastes that were in contact with the blood of patients undergoing hemodialysis, including contaminated disposable equipment and supplies such as tubing, filters, disposable sheets, towels, gloves, aprons, and laboratory coats.

9) Discarded medical equipment and parts that were in contact with infectious agents.

10) Biological waste and discarded materials contaminated with blood, excretion, exudates or secretion from human beings or animals who are isolated to protect others from communicable diseases."

11) Other waste material that results from the administration of medical care to a patient by a health care provider and is found by the Administrator to pose a threat to human health or the environment.

EPA data collection efforts with respect to disease-causing and injury potential will not focus on epidemiological studies. The Agency will obtain these data from the Agency for Toxic Substances and Disease Registry (ATSDR) report on incidence of injuries and infection from occupational settings and public exposure to medical waste. However, the Agency recognizes the importance of epidemiology in assessing the risk of infection. As alluded to earlier, disease results from the interaction of several factors, not just the presence of pathogens. Therefore, epidemiological data are an important link in assessing whether a mechanism exists for the transfer of pathogens from objects or materials to a susceptible host. ATSDR data should provide the important epidemiological evidence needed to better assess the disease-causing and injury health hazards posed by medical waste. The Agency will incorporate available ATSDR findings into its subsequent interim medical waste report and final report to Congress.

2.5 General Approach to Evaluating Health Hazards Posed by Exposure to Medical Waste

The following section describes EPA's approach to determining present and potential health hazards posed by medical waste. If all of the information needed below is available, then a quantitative risk assessment may be feasible.

Infection Hazards

To assess the infectious nature of medical waste, the Agency will evaluate its potential to cause disease in humans. This approach emphasizes the microbiological content of medical waste and possible exposure scenarios; it does not consider aesthetic concerns. Once the Agency has evaluated the disease-causing potential of medical waste, we will evaluate the relationship between microbial activity and disease transmission.

The section below describes the methodology for categorizing medical waste according to its potential to contain microorganisms capable of causing disease (i.e., pathogens). The approach focuses on the categories of listed medical waste (as defined in the statute) and any other categories of medical waste identified by EPA. Sections 2, 3, and 4 address an approach to determining the disease-causing potential of each category (and subcategory) of medical waste that may contain pathogenic organisms. The methodology includes identifying pathogens present in medical waste and evaluating microbial activity and expected disease causation from exposure to the pathogens. In evaluating disease-causing potential, the Agency will investigate possible human exposures from a range of medical waste management and mismanagement scenarios.

Identify and Categorize Medical Waste

The Agency will consult with hospitals and professional trade associations, and conduct a search of the available literature to establish a comprehensive list of wastes generated by medical, research, and industrial facilities from "the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals." Once the universe of medical waste is identified, the Agency will determine which wastes, if any, were not included in the categories listed in the statute. Additional categories will be established as appropriate for the health assessment.

Each category will be evaluated for its potential to contain organisms capable of causing disease and will be designated as either infectious, potentially infectious or non-infectious. If a specific category cannot be so designated due to differing biological activity or physical characteristics of wastes within the category, the Agency will divide the category into subcategories using these characteristics as the basis. For example, category 1 ("Cultures and stocks of infectious agents and associated biologicals . . . and devices used to transfer, inoculate, or mix cultures") includes wastes which meet both of these criteria. Cultures and stocks are concentrated solutions of organisms. Devices used to transfer these cultures may be only marginally contaminated with organisms. Thus, based on differing physical forms and microbial activity, the Agency may establish two subcategories. Cultures and stocks may be designated as infectious. Devices used to transfer cultures may be considered as potentially infectious.

Identify Types of Pathogens Present in Medical Waste and Associated Disease-Causing Potential

The Agency will search available information sources to identify specific pathogens or classes of pathogens expected to be present in medical waste categories and subcategories designated as potentially infectious and infectious. For example, dialysis wastes may only be contaminated with blood borne pathogens, such as HIV and HBV. Once the spectrum of expected pathogens in each category and subcategory of medical waste has been determined, a profile of diseases, injuries or other factors influencing health will be identified for each pathogen. The Agency will gather needed information from data bases and representatives of the following organizations and agencies to determine diseases associated with each type or class of pathogen:

- American Medical Record Association
- Armed Forces Institute of Pathology (AFIPS)
- Centers for Disease Control of the Public Health Service, CDC,PHS
- National Center for Health Statistics (NCHS)
- National Library of Medicine (NLM)

- World Health Organization (WHO)
- Others as appropriate or identified

Following identification of a disease, taking into consideration the potential concerns regarding the presence of certain organisms in medical waste, the Agency will determine the risk of disease transmission associated with exposure to class pathogens by age and sex of the affected individual. Most diseases are characterized by unique frequency patterns of morbidity and mortality rates within the varying age groups and sexes. Whenever possible, the Agency will obtain these figures from the National Center for Health Statistics and CDC. If numeric estimates are inadequate for use in the evaluation, the Agency will consult additional sources such as the American Association of Health Data Systems, the Association for Health Records, and the Commission on Professional and Hospital Activities.

The overall approach to determining the disease-causing potential of pathogenic organisms present in medical waste relies heavily on the availability of data. If data on microbial content are inadequate for making the determination, the Agency will consider developing a reasonable analytical strategy to determine the potentiality of infectious medical waste that may contain one or more classes of pathogenic organisms typically associated with outbreaks of disease in the United States.

Estimate Concentration of Pathogens

The Agency will use available information sources to estimate quantities of pathogenic organisms present in each group of potentially infectious and infectious waste. These data will be used to determine whether pathogens are present in sufficient quantities or doses to cause disease provided there is a susceptible host and a route of transmission. However, any discussion of pathogen dose must include the interrelationship of factors such as temperature, pH, radiation (e.g., ultraviolet), and relative humidity, host susceptibility immune status, and route of exposure which directly affect pathogen growth and viability.

Relationship Between Medical Waste Microbial Activity and Disease Transmission

To determine the probability or likelihood that a person exposed to a pathogen in medical waste will develop a specific disease as a result of that exposure, it will be necessary to evaluate factors relating to the transmission of disease. The ATSDR effort will be used to provide these data wherever possible. Information on disease transmission may be available from EPA files, OSHA, CDC, and other government agencies. The minimum information needed will include but will not be limited to:

- identification of possible modes of transmission (e.g., direct contact such as a needle stick, indirect contact such as airborne transmission, or vector borne transmission such as insect bites),

- concentration of each pathogen per unit of medical waste in each exposure scenario,
- infective dose for each pathogen (dose needed to induce the related disease),
- age- and sex-specific susceptibility of the disease and individual and population ("herd") immunity to the disease.

The Agency recognizes that the minimum data required to evaluate disease transmission may not be available, and when these minimum data are not available, for example, blood or other tissue waste containing HIV virus, it will be necessary to extrapolate from the available information. The Agency will describe different mixes of transmission factors generated from available facts combined with current theory on occurrence of infection. The weight of evidence from epidemiological data that supports each theory will be used to estimate alternative likelihoods for the theoretic dose/response relationships. This procedure should provide a subjective basis for making policy decisions.

Evaluation of Other Hazards Posed by Medical Waste

The Agency will also assess hazards posed by sub-categories of medical waste designated as "non-infectious". This group includes materials that are not expected to contain or have not been in contact with infectious agents.

The Agency will use ATSDR data where possible in assessing hazards posed by the "non-infectious" group of medical waste. In the absence of data, the Agency will provide a subjective assessment of the hazards based on the judgments and opinions of health care experts and professionals.

2.6 Evaluation of Health Hazards Posed by Incinerating Medical Waste

Incineration of medical waste is a very common method of treating refuse from hospitals, biomedical research laboratories, and similar institutions. Such wastes may be incinerated on-site or transported off-site to regional, municipal, or commercial waste incinerators. Hospital wastes include both infectious wastes (i.e., wastes that contain pathogens with sufficient virulence and quantity such that exposure to the wastes could result in infectious disease) and non-infectious or general housekeeping wastes. "Hospital wastes" are generated at a number of medical facilities, including hospitals, clinics, research facilities, geriatric care facilities, medical test facilities, and physicians' offices. Approximately 500,000 tons of "hospital waste" are generated each year. It is currently estimated that approximately two thirds of the hospitals in the United States have incinerators.

The potential sources of risk to the general population from medical waste combustion medical incinerators are pathogens (in stack or fugitive emissions, or ash residues), organic chemicals, carbon monoxide, particulate matter, metals (As, Cd, Cr, Hg, and Pb) and acid gases (hydrogen chloride, sulfur dioxide, and nitrogen oxides). Of the groups of microorganisms (viruses, bacteria, fungi, protozoa, and helminths), bacteria, particularly spore formers, are believed most likely to survive in medical waste. Whether or not bacteria would survive the incineration process has been tested in a number of studies. One study compared bacteria collected from stack emissions with bacteria collected from the ambient air and found no significant difference between them. While bacteria were not measured in the waste material burned, the authors concluded that the presence of bacteria in emissions indicated that they originated in excess ambient air that had been added to the secondary combustion chambers, and did not spend sufficient time exposed to high temperatures to inactivate them.[1] Currently, EPA is developing standard methods to test for pathogen emissions.

A second study used a composited sham waste that was inoculated with cultures of Bacillus subtilis, a spore-forming nonpathogenic bacterium, and then incinerated with a burn cycle time of 20-30 minutes and a temperature of 760 degrees C. A number of species of bacteria were isolated from the stack gas. However, no B. subtilis were found, indicating that the inoculated bacteria had been destroyed, and that the species present may have originated outside the waste source. The authors postulated that the other species came into the incinerator from the room housing it, and analysis of this air, in fact, accounted for 91 out of 96 colonies found in the stack emissions.[2] The authors did not address whether or not the species found arose from waste that was previously or currently present in the room.

The studies did not evaluate pathogen survival in ash. However, pathogens may survive in the ash residue of an improperly operated incinerator where the mass of waste to be burned does not remain in the primary chamber for a sufficient time for adequate temperatures to be reached throughout the waste. Variables affecting pathogen survival include moisture content, capacity, loading rate, and water formed during combustion.

Performing a quantitative risk assessment would be extremely difficult due to the diversity of incinerator types used, the range of operating conditions and waste loads, the lack of dose-response data, and the lack of exposure assessment information. There is a need for both pathogen emission measurements from stacks and microorganism concentration measurements in bottom and fly ash. These measurements are needed not only under experimental conditions that involve different kinds of incinerators, under varying operating conditions, but also of incinerators in actual use under normal operating conditions. Ambient air sampling (measuring both indicator organisms and organisms found in pre-incineration wastes) is also required for exposure assessment at sites near hospital and municipal incinerators burning medical wastes.

Given the difficulty of performing a quantitative risk assessment, EPA may explore development of a testing protocol whereby spore-forming bacteria cultures are added to the waste and then measured in the emission and residues. The incinerator operating parameters would then be adjusted for complete spore destruction. If such spores are eliminated, it could be assumed that no other microorganisms in the waste would survive.

Typically, existing hospital incinerators are designed to operate at lower than optimum combustion temperatures and residence times; and, hence, do not achieve optimum combustion control. Also, the operators of many existing hospital incinerators are not trained to properly load and operate the incinerators. These design and operational deficiencies in many existing hospital incinerators result in increased emissions. Further, most existing facilities do not have add-on controls.

The Agency has prepared a report entitled Hospital Waste Combustion Study: Data Gathering Phase (EPA-450/3-88-017) which summarizes available information on hospital waste incinerators, including the available data on air emissions. The data presented in the report include measured emissions of organics (dioxins and furans), carbon monoxide, particulate matter, metals (arsenic, cadmium, chromium, and lead) and acid gases (sulfur dioxide and hydrogen chloride). There is only limited information in this study on the constituents of ash from the incineration of hospital waste. The study does not include estimates of air exposure levels and risks of cancer or noncancer effects associated with exposure to stack emissions from hospital incinerators or fugitive dust emissions from the handling of ash.

The Agency is in the process of expanding the emissions and control technology data base to determine whether a new source performance standard for new medical waste incinerators (MWIs) should be proposed under Section 111 of the Clean Air Act. Section 111 of the Clean Air Act directs the Administrator to establish NSPS for any category of new stationary source of air pollution which ". . .causes or contributes significantly to air pollution which may reasonably be anticipated to endanger public health or welfare." The Act requires that NSPS reflect ". . .the degree of emission limitation and the percentage reduction achievable through application of the best technological system of continuous emission reduction which (taking into consideration the cost of achieving such emission reduction, any nonair quality health and environmental impact and energy requirements) the Administrator determines has been adequately demonstrated." The NSPS apply only to stationary sources, the construction or modification of which commences after the NSPS are proposed in the Federal Register.

To determine the level of performance achievable with the best demonstrated technology, EPA plans to test up to four modern, controlled-air facilities equipped with a cross section of candidates for best available add-on control technologies. Some of this testing will be performed using general hospital waste as the incinerator feed and some with "red-bag" (infectious, biomedical waste) feed. One test is planned when the incinerator feed contains cytotoxins. Emissions of particulate matter, hydrogen chloride, carbon monoxide, carbon dioxide, sulfur dioxide, nitrogen oxides, metals (arsenic, cadmium, chromium, lead), total hydrocarbons, and dioxins/furans, will be measured. Constituents of ash from incineration of medical waste will also be analyzed. Pathogen destruction will be assessed by "spiking" the feed with a known heat-resistant spore and then sampling for this spore in the air, water, and ash streams. The incinerator secondary combustion chamber temperatures will be varied to allow assessment of this variation on emissions from the incinerator tested. Testing of these incinerators is scheduled to begin in April 1990 with data analysis to be completed by mid-1991.

The source information and emissions data gathered for new medical waste incinerators will subsequently be used to conduct a risk assessment for inclusion in the final report to congress required under 11008 of RCRA. This assessment will be initiated after completion of the data analysis in support of the new source performance standards and will use all data on new hospital incinerators that are available to EPA at that time (mid-1991). No data are available to conduct a risk assessment for the older existing hospital incinerators. The Agency is, however, evaluating the need to conduct such studies and determining what additional resources would be necessary.

Section 111 also provides for control of existing sources under Section 111(d). Section 111(d) procedures are invoked whenever an NSPS is set for an air pollutant that is not regulated or on a list to be regulated by national ambient air quality standards or national emission standards for hazardous air pollutants. Pollutants qualifying under this criteria are termed "designated pollutants." EPA also issues emission guidelines for existing sources within the source category regulated by the NSPS. Upon promulgation of the emission guidelines for the designated pollutants, a process is commenced, similar to the State implementation plan process, whereby each

State submits to the Administrator a plan establishing emission standards and compliance schedules for existing sources within their jurisdiction. The State plan must apply to the designated pollutant and the source categories covered by the NSPS. The Agency has made a preliminary determination not to include a standard for a designated pollutant.

EPA's review of medical waste incinerators, will involve three principal phases of activity: (1) information gathering, (2) analysis of the information as required by the MWTA and risk assessment, and (3) development of the NSPS. EPA will consider the following options to limit emissions from medical waste incinerators: (1) the development of a new source performance standard (NSPS), (2) the development of an operator training program for new and existing medical waste incinerators, (3) the consideration of using best available control technology (BACT) guidance for the voluntary use of State and local agencies prior to our proposal of the NSPS, and (4) the possibility of controlling existing sources. The Agency is gathering emissions data from existing and new incinerators. The information collected about the industry and the pollutants emitted will be used in analytical studies to determine whether an NSPS is needed for this industry. We will conduct studies to determine costs, economic, environmental, and energy impacts of various regulatory alternatives. Should EPA determine that an NSPS is needed, several control alternatives will be considered, including operator training, good combustion controls, wet scrubbers, and dry scrubbers, followed by fabric filters or electrostatic precipitators. The most plausible regulatory alternative will be selected based on the results of the studies. Materials separation could also be a component of Best Demonstrated Technology (BDT) as a control strategy for municipal waste incinerators (MWCs) proposed under the Agency's NSPS for MWIs.

In summary, the Agency is in the process of expanding the emissions and control technology data base for medical waste incinerators to support the development of a new source performance standard for new incinerators. The need for medical waste incinerator regulations is based on: (1) our recently completed report which characterizes hospital waste and examines available information on medical waste incinerators and (2) the anticipation that the Medical Waste Tracking Act will cause more waste to be incinerated and focus public attention on the emissions.

2.7 Evaluation of Health Hazards Posed by Landfilling Medical Waste

The Agency will research information sources to determine whether disposal of medical waste in sanitary landfills has resulted in or could potentially result in hazards to humans or the environment. The Agency will seek information on the fate and transport of pathogenic microorganisms in soils (i.e., the landfill environment), groundwater, and surface water.

2.8 Evaluation of Health Hazards Posed by Disposal in Sewage Systems

The Agency will research information sources to determine whether disposal of medical waste in sewage disposal systems has resulted in or could potentially result in hazards to humans or the environment. The Agency will seek information on the fate and transport of pathogenic microorganisms through sewage disposal systems.

2.9 Data Gaps and Research Needs

As discussed earlier EPA will evaluate whether sufficient information exists to address the questions posed by Congress adequately. If minimum data needs cannot be fulfilled, the Agency will propose research activities to obtain such data.

2.10 Potential Health Hazards Associated with Handling Medical Waste

To assess the potential hazards to the environment, the Agency will use a similar process as described for assessing hazards to human health. The Agency will discuss its progress in the subsequent interim report to Congress.

2.11 References

1. Kelley, H., G. Brenniman, and J. Kusek. "An evaluation of bacterial emissions from a hospital incinerator" in Proceedings from VIth World Conference on Air Quality, Volume 2, May 1983.

2. Allen, R., G. Brenniman, R. Logue, and V. Strand. "Emission of Airborne Bacteria from a Hospital Incinerator", Journal of the Air Pollution Control Association, Vol. 39, No. 2, 1989.

CHAPTER 3

ESTIMATED COSTS OF THE DEMONSTRATION PROGRAM AND IMPROPER MANAGEMENT OF MEDICAL WASTES

This chapter discusses EPA's efforts to date to estimate "the present and potential costs (A) to local economies, persons, and the environment from improper handling, storage, transportation, treatment or disposal of medical waste and (B) to generators, transporters, and treatment, storage, and disposal facilities from regulations" promulgated under the MWTA. This discussion will include the methodology and results of the Agency's preliminary cost analysis, and some of the sources of information EPA expects to use in refining these cost estimates for the final report.

EPA has analyzed the costs of the regulation with available data. The cost analysis includes cost estimates for management practices required by the demonstration program for the five States participating in the program (Connecticut, New Jersey, New York, Puerto Rico, and Rhode Island). These costs differ from what was stated in the preamble to the rule, since the earlier costs were estimated for the ten states originally targeted for involvement. In this cost analysis, state administrative costs, as well as potential indirect costs associated with changes in waste management practices, have not been analyzed; their combined effects on the costs of the rule are unclear. Information from the demonstration program and comments received on the inter. final regulation will be used to refine these estimates.

Estimation of the costs associated with improper management of medical wastes are more difficult to develop. EPA has developed two preliminary estimates of costs associated with improper management of medical wastes—those costs to beach users from lost beach days, and a quantitative estimate of the inherent value of clean beaches to State residents,[1] which are discussed in section 3.6. Currently there is not enough information available to develop precise estimates of the quantity of improperly managed medical waste each year, or the resulting impact on "local economies, persons and the environment from improper handling, storage, transportation, treatment or disposal of medical wastes." EPA is working to develop a better understanding of these factors, and hopes to develop rough cost estimates as these factors become better defined.

3.1 Cost Methodology

The methodology presented here for estimating the costs "to generators, transporters, and treatment, storage, and disposal facilities from regulations" setting up the tracking program estimates only the direct costs incurred through compliance with the rule for the five states currently participating in the demonstration program. The methodology involves the following steps: (1) characterizing the regulated community in terms of the numbers and types of generators in the ten states, and the numbers of transporters affected; (2) estimating the medical waste generation rates for each of the generator types and their rate of waste shipments transported off site; (3) accounting for both current state regulations and existing waste management practices governing medical wastes that are similar to the requirements of 40 CFR Part 259; and (4) estimating direct compliance costs for packaging, tracking, generator recordkeeping for generators of less than 50 pounds of regulated medical waste per month, transporter recordkeeping and reporting, and incinerator recordkeeping and reporting.

This cost analysis does not address the potential indirect cost effects of the tracking system. For example, medical waste disposal capacity in the demonstration states may be reduced if landfill facilities become more reluctant to accept medical wastes; the combination of packaging, labeling, and tracking requirements may cause increasing numbers of landfill owner/operators to refuse handling medical wastes. As a result, medical waste disposal costs could increase. On the other hand, increased use of alternate treatment technologies may decrease the volume of waste regulated under the tracking rule, and thus may decrease compliance costs. For example, both on-site incineration and treatment and destruction exclude waste from the Part 259 requirements. Information on changes in waste management practices, as the demonstration program continues, may indicate some of the indirect economic effects of the rule.

Some of the estimates discussed in this chapter vary slightly from those in the preamble discussion of the Medical Waste Tracking Rule (54 FR 12326). This is because EPA has refined estimates for some of the input variables (e.g., waste generation rates, frequency of shipments) and the universe has changed.

3.2 Characterizing the Regulated Community

In order to estimate the direct compliance costs imposed on the regulated community by the federal medical waste tracking rules, the regulated community is divided into three groups: medical waste generators, transporters, and treatment and disposal facilities.

Generators

The major generators of medical wastes, that are potentially subject to regulation fall into ten types (nine specific generator types and "other generators"), listed in Table 3-1. Chapter 1 describes the methodology used to develop these generator types. However, the generator estimates in Chapter 1 are national estimates, whereas the generator estimates given here are EPA's estimates of the number of generators (by type) in the five states. The waste generation estimates are the same for both chapters.

EPA obtained most of the data on the numbers for each generator type in each of the five states from the Department of Health and Human Services and professional associations (e.g., the American Medical Association, and the American Dental Association, etc.). The preamble to the Part 259 regulations (54 FR 12366) explains some of these estimates in more detail. EPA

TABLE 3-1
Generator Types and Characteristics

Generator	Number	Waste Per Month Per Gen. (lbs)	Shipments Per Year Per Gen.
Hospitals	560	8,800	260
Physicians' Offices	24,907	50	12
Dentists	21,779	25	12
Nursing Homes	1,225	400	12
Clinics	1,647	100	26
Medical Laboratories	549	600	52
Funeral Homes	3,062	25	12
Veterinarians	4,081	25	12
Blood Banks	161	400	52
Other	2,500	25	12
Total	60,471		

SOURCE: References 2-10

recognizes that these estimates are preliminary and is continuing to collect more detailed information to further refine these estimates. Other medical waste generator groups, besides those included in this analysis, may exist; EPA requested comment and input on these additional generator types.

Transporters and Treatment/Disposal Facilities

The Agency has limited information concerning the number of transporters and treatment and disposal facilities. Data on the number of transporters affects cost estimates, because the total transporter reporting requirement costs are dependent on the number of transporters that must submit such reports. Information on transporter numbers is complicated by the fact that medical waste transporters often operate in multiple states and some states have no licensing requirements for transporters. EPA estimates the total number of transporters, based on notifications to EPA, in the five participating States to be approximately 180. For the purposes of this analysis, the number of treaters and disposers has no impact on costs, since their costs are a function of the number of shipments.

3.3 Medical Waste Generation Rates

Table 3-1 presents the estimated average quantity of regulated medical waste generated by an average facility within each generator type. The facility size and the waste generation rates vary significantly within generator types, particularly for hospitals. In estimating waste generation rates for hospitals, EPA estimated an average per bed waste generation rate, coupled with data on numbers of beds and hospitals, to determine waste generation. The methodology used to develop the nationwide waste generation estimates in Chapter 1 is the same methodology that was used to develop these generation rate estimates for the five states analyzed here.

The total number of shipments for each generator category is based on available waste generation rates and from interviews with both generators and transporters. EPA estimates that hospitals ship out waste five times per week, blood banks and medical laboratories once a week, and the remaining generator categories either once every other week or once a month. Table 3-1 summarizes waste generation and waste shipment rate estimates.

3.3 Regulatory Costs

To estimate direct compliance costs, EPA first divided each of the major requirements of the rule into its component tasks and estimated the labor hours and material costs associated with completion of each task. The requirements of the rule fall into five tasks: packaging, tracking, incineration recordkeeping and reporting, generator recordkeeping (for generators of less than 50 pounds per month), and transporter reporting and recordkeeping. Costs for the first four tasks are estimated for generators; only costs for tracking are estimated for transporters and disposers.

Medical waste generators have voluntarily adopted a number of current waste management practices that are substantively similar to the requirements set forth in the tracking rule. Where this cost analysis accounts for these baseline practices, reduced or eliminated materials costs or required task times result. For example, the cost analysis assumes that generators already segregate sharps and fluids; it applies no additional compliance costs (for either materials or labor time) for this requirement of the rule. In addition, this costs analysis accounts for existing State regulations that are similar to the tracking rule. Where State requirements are similar to the tracking rule, no incremental cost is assigned in that State for that particular requirement. For purposes of this analysis, EPA used the State requirements in effect while the 40 CFR Part 259 regulations were being developed. Although New York and New Jersey have since rewritten State requirements to reflect the tracking rule, these recent changes are not incorporated into this cost analysis; EPA assumes these revisions are a direct result of the tracking rule, and thus costs for these State requirements are actually incremental costs to the federal rule.

The assumptions used regarding State requirements are described in more detail in the preamble to the interim final regulations (54 FR 12368) and in the background memo submitted to the docket, Estimates of Costs for 40 CFR Part 259," October 1989. The costs estimated for complying with each component of the rule are described there as well; some of the cost estimates have been refined since publication in the Federal Register.

3.4 Results

During the two-year demonstration period, the tracking rule will impose average annual compliance costs of approximately $12 million, for a total estimated 2-year program cost of $24 million (undiscounted). Table 3-2 summarizes estimated compliance costs by component and generator type for the original ten states.

The results indicate that physicians' offices, due to their large number, and hospitals, due to their high medical waste generation rate, together account for over one-sixth of all costs. EPA estimates that all generators combined bear approximately one-third (70 percent) of the total costs of the tracking rule, with the remaining costs divided between transporters and disposers.

The following paragraphs will discuss costs for specific requirements of the rule. The average costs are estimated based upon total cost of the rule in the five participating states. These averages include facilities located in states where some requirements of the rule are already required by the state and therefore assigned as baseline costs and not incremental costs--not included in this analysis. Thus, for instance, while the average cost overall for physician offices is $36 dollars per facility, the average cost of a facility located a State where no requirements are assumed in the baseline is $144 per facility. Likewise, the average cost of a physician office, located in a State where all the rule's requirements are assumed as baseline costs, would be zero.

TABLE 3-2
Cost Summary—Annual Costs (in Thousands)[a]

Regulated Community	Packaging Req.	Manifest Req.	Incin. Req.	Reporting Req.[b]	Total
Hospitals	580	90	500	0	1,170
Physicians' Offices	360	250	0	280	900
Dentists	150	200	0	250	590
Nursing Homes	160	30	0	10	190
Clinics	50	60	0	20	130
Medical Laboratories	170	90	0	10	260
Funeral Homes	10	20	0	40	70
Veterinarians	30	20	0	70	110
Blood Banks	20	20	0	0	30
Other	50	80	0	30	140
Transporters	0	4,910[c]	0	0	4,910
Disposal Facilities	0	3,410	0	0	3,410
Total	1,560	9,150	500	690	11,910

SOURCE: References 2 - 11

[a] Cost may not add due to rounding.
[b] For generators of less than 50 pounds per month.
[c] Average annual cost over the 2 years of the demonstration program.

EPA estimates that the overall average compliance costs of the tracking rule on a per generator facility basis range from $2,093 per year for hospitals to $22 per year for funeral homes. EPA estimates that the average incremental cost per pound of generated medical waste for these same two generator categories is $0.02 for hospitals and $0.07 for funeral homes. The lower per pound cost for hospitals is due to the fact that hospitals frequently incinerate their waste; also, hospitals dispose of more waste per shipment and, therefore, their per-pound tracking costs are lower than funeral homes. The cost analysis estimates that the average incremental cost to generators in all the generator categories is $0.04 per pound of regulated medical waste.

The highest per facility compliance cost is estimated for hospitals that do not incinerate their waste and that do not currently meet the requirements of 40 CFR Part 259. For a "typical" hospital (one that generates an average of one ton of medical waste per week), the estimated highest cost is $16,723 per year. In contrast, a facility that generates more than 50 pounds of regulated medical waste per month and already meets the Part 259 requirements will have no additional compliance costs.

The packaging requirements are likely to impose costs of approximately $1.6 million per year. The amount of waste generated per year for all generators in a category is the driving force behind the costs for this component; thus physicians' offices and hospitals together account for over half of the total packaging costs. The remaining eight generator categories incur estimated aggregate annual packaging costs that range from $12,000 for funeral homes to $173,000 for medical laboratories.

The costs of compliance with the tracking requirements ($9.0 million per year) account for approximately three-fourths of the total compliance costs. EPA estimates that the generators will incur approximately $838,000 of these tracking costs per year. Physician offices will account for $251,000 of this estimate, dentists will account for $201,000, and the remaining eight generator categories account for less than $100,000 each. The additional tracking costs are distributed between transporters and disposal facilities. Transporters incur average annual tracking system costs of approximately $4.8 million, and disposers incur approximately $3.4 million. Included in the transporter costs is a one-time requirement to notify EPA of intent to transport regulated medical wastes, the cost of which will total approximately $3,000.

Incinerator recordkeeping and reporting requirements will total approximately $504,000 for the estimated 375 hospitals in the participating States that currently use on-site incinerators.

Generators of less than 50 pounds per month of regulated medical waste, although usually exempt from the tracking requirements, are required to maintain a log of their generated wastes. This requirement will impose relatively small costs on these generators ($691,000 per year in aggregate). For example, the estimated 12,454 physician offices that are generators of less than 50 pounds of regulated medical waste per month will have recordkeeping costs of approximately $281,000 (or $23 per office) per year.

3.5 Sensitivity Analysis

These estimates may understate actual costs. For example, transport vehicle and disposal costs are assumed to be unchanged. For various reasons, landfills are apparently less willing (and in some cases unwilling) to accept medical waste, a phenomenon which suggests that the rule will increase disposal costs two additional ways. First, landfills willing to accept regulated medical waste will be able to charge more for the service. Second, the increased cost of land disposal will stimulate the demand for incineration.

Limited information suggests that the current price for medical waste incineration is about $0.30 per pound.[12] Based on Table 3-1, about 56 million pounds of regulated medical waste (that is not currently incinerated on-site) are generated per year in the states targeted for participation in the program. Assuming constant returns to scale in incineration, every 1 percent of this waste shifted from land disposal to off-site incineration will increase total costs by about $169,404 per year. Thus, if just 10 percent of the medical waste is shifted to off-site incineration, the annual cost of the rule will be about 14 percent higher than estimated. Savings from avoiding landfill disposal fees, increased on-site management, and alternative treatment technologies will offset this amount, while limited incineration capacity combined with increased demand will tend to increase it.

In addition, the cost analysis does not estimate the effects of §259.73, which requires regulated medical waste to be transported in a leak-resistant, fully enclosed, cargo-carrying body that is maintained in good sanitary condition. However, the rule does not prohibit the transport of regulated medical waste simultaneously with other waste. The Agency does not have data to analyze rigorously how these transporter vehicle requirements will affect current practices and costs. However, limited information supplied by transporters and generators indicates that in many instances medical wastes are already transported in vehicles meeting the Part 259 requirements. To the extent that current practices do not reflect these requirements, transporter costs will be incurred.

The cost figures provided here are meant to be rough estimates of the actual costs of implementing the management standards and tracking requirements in the tracking rule. In future reports, the cost estimates will be refined as new data are obtained. The Agency has encouraged generators, transporters, and disposers to submit cost information that they consider relevant to assessing the actual costs of the demonstration program.

3.6 Cost of Improperly Managed Medical Waste

EPA is working to identify impacts to "local economies, persons and the environment from the improper handling, storage, transportation, treatment or disposal of medical waste." Although the Agency has not currently quantified the costs of each of these threats, they may be significant. The "present or potential threat to human health and the environment posed by medical waste or the incineration thereof" is discussed more thoroughly in Chapter 2 of this report.

EPA has developed preliminary cost estimates for the impacts on persons of the appearance of medical wastes on the beaches in states proposed for inclusion in the demonstration program. For the purposes of this particular cost analysis, EPA assumed that all medical wastes appearing on beaches is waste which will be regulated by the tracking rule. Data sources on which to base this analysis are sparse, and the Agency has estimated costs based on limited data.

The Agency recognizes that the sources of beach wash-ups are not certain. A recent study [13] suggests that combined sewer overflows and transfer operations at municipal solid waste landfills located near water bodies contribute to the problem. Moreover, household waste generators, a known source of "medical-like waste" found on beaches, are excluded from the definition of "medical waste" by statute. Wastes falling into this category include insulin syringes used at home and other medical wastes generated at home. The management and disposal of these sources of medical wastes will not be regulated by the tracking rule. Therefore, it is likely that the 40 CFR Part 259 regulations may not directly or significantly affect these potential sources for washups.

For purposes of assessing related costs, the Agency developed two approaches. The methodology used for these two approaches is detailed more fully in the March 1990 memo, "Methodology for Costs and Benefits Analysis for the First Interim Report to Congress on Medical Waste." The two methodological approaches are simplistic, but do provide some quantitative estimation of the effects of medical waste. The first approach is based on value of clean beaches that accrue specifically to beach users (e.g., sunbathers, swimmers, strollers). It uses an estimate of the economic value of a beach-day visit and the number of lost beach-day visits due to medical waste wash-ups. The second approach is based on a broader range of losses due to medical waste wash-ups that accrue not only to beach users, but also to other groups such as those who value the option to visit the beach and those among the general population who are not completely indifferent to the fact that medical waste is washing up on the nation's beaches. Both methodologies involve simple extrapolations based on rough approximations of the relevant parameters. They are therefore extremely sensitive to the assumptions used and are, at best, accurate by perhaps an order of magnitude.

The first method estimates the economic value of beach day visits lost due to medical-waste related beach closings in Connecticut, New York and New Jersey at approximately $30 million. This figure is obtained by extrapolation based on very limited data concerning New Jersey beach visitation. The second approach uses a different method of extrapolation to obtain an estimated loss of $39 million for the five states participating in the demonstration program. In both cases, the 40 CFR Part 259 regulations were assumed to eliminate all beach closings due to medical waste. As indicated, however, the program is not expected to significantly reduce the nonregulated medical waste wash-ups. It should also be noted that some of the beach closings which did occur during the summer did not involve medical waste but were instead attributable to general refuse and poor water quality.

3.7 References

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CHAPTER 4

DEMONSTRATION PROGRAM OBJECTIVES AND EVALUATION

This chapter evaluates the success of the demonstration program, and outlines the other available and potentially available methods for tracking medical waste. Sections 4.1 through 4.3 discuss the objectives and goals of the MWTA and demonstration program, measures for evaluating its success, and overall conclusions about the success of the program. Section 4.4 discusses the Agency's plans to evaluate changes in management practices attributable to the demonstration program. Sections 4.5 and 4.6 describe other tracking methods available.

4.1 Objectives of the MWTA

As stated in the preamble to the interim final rule, the MWTA was enacted due to health and environmental concerns arising from medical waste. These concerns included the degradation of shoreline areas from wash-ups of waste, particularly in Connecticut, New Jersey, and New York during the summer of 1988. Public safety concerns were created by reports of careless management of medical waste, such as in open dumpsters. The Act was intended to be a first step in addressing these problems.

The primary objective of the MWTA is to ensure that regulated medical wastes which are generated in a Covered State and which may pose environmental (including aesthetic) problems are delivered to disposal or treatment facilities with a minimum of exposure to waste management workers and the public. The

Agency issued interim final rules on March 24, 1989 that established a regulatory program to accomplish this objective. The tracking rule itself helps to ensure that waste reaches the proper destination since it requires accounting of all waste transported, and makes effective civil and criminal sanctions for violation. Additionally, the regulations will ensure that regulated medical wastes will be packaged securely and labeled and marked. Proper packaging reduces the chances of waste handlers and the public being exposed to these wastes. Labeling and marking ensures easy identification of regulated medical waste will help deter the improper management of the waste and make it more likely that the waste will be handled with greater care than general refuse.

However, the specific requirements in the tracking rule may not significantly reduce the amount of medical waste deposited on beaches, which was the principal concern behind the Act. The MWTA does not address several sources of medical waste which are known to contribute significantly to beach waste wash-ups. These sources include household medical care and intravenous drug use. It would not be appropriate to judge the success of the demonstration program in tracking medical waste, based solely on the amount of medical waste washing up on beaches. The Agency intends to evaluate the success of the overall program (both regulatory and nonregulatory) in:

- tracking and managing medical wastes that fall within the scope of the Act, i.e., wastes from institutions and commercial sources.

- addressing the medical waste problem in general, i.e., beach wash-ups, mismanagement of home health-care wastes.
- collecting and evaluating information to better understand the problem.

4.2 Measuring Effectiveness

Demonstration Program Operations

The first set of criteria to measure success concentrates on the operations of the demonstration program. The program's primary focus is on medical waste handled off-site in Covered States. Four areas are discussed: State participation, compliance, regulatory analysis, and recreational and occupational injuries. For each area, the information the Agency plans to report on in subsequent reports is described. In addition, information currently available is provided.

State Participation

The MWTA is designed to be implemented jointly by EPA and the States. EPA was directed to establish a program for tracking medical waste and to list the types of medical wastes to be tracked. Participation in the demonstration program was determined by the States. The ten States covered in the MWTA (New York, New Jersey, Connecticut, and the States contiguous to the Great Lakes) were in the demonstration program unless they opted out. New York, New Jersey, and Connecticut could only opt out if they had implemented a medical waste tracking program that was no less stringent than the federal program, while the Great

Lakes states could opt out by making a written request. All other states had the opportunity to be included in the demonstration program by petitioning the EPA Administrator.

The Great Lakes States all opted out of the program. The major reasons why the Great Lakes states opted out are that they had already enacted or were in the process of enacting state programs tailored to their specific needs, and that they had limited funding available to implement the relatively low priority program.

Many of the Great Lakes states were already well on their way to developing or implementing regulations that they believed to be more appropriate for their respective states. (Tracking mechanisms vary from an eight part form in Pennsylvania to no tracking mechanism in Connecticut, Indiana, Michigan, Minnesota, Ohio, Pennsylvania, and Wisconsin.) States voiced concern that new Federal requirements would conflict with existing state laws and regulations; also, they felt it would be difficult to get their legislature(s) to repeal existing State regulations to enact a program of short (two years) duration.[1] A general concern was that the cost to implement the federal regulations (e.g., the tracking form) would be more costly than the program's benefits justified. Nonetheless, the Act seems to have encouraged a great deal of legislative and regulatory activity in the Great Lakes states. In addition, Rhode Island and Puerto Rico decided to opt-in to the program.

The success of the demonstration program is dependent on strong state implementation of the program. The demonstration program cannot be accurately assessed without taking into account the implementation activities of the States. In subsequent reports, the activities undertaken by each Covered State will be briefly described.

Compliance

The extent of compliance with the tracking program may have a significant effect on the demonstration program's success, and it would be very difficult to assess the impact of the program if noncompliance is widespread. Generators' compliance with packaging requirements will affect public and worker exposure to medical waste. Exception and discrepancy reports are essential for EPA to investigate stray shipments and deter illegal dumping. EPA will work with the participating States to determine what parts of the rules have been difficult for parties to comply with and for EPA and States to enforce. In order to determine the extent of compliance, EPA and the states will be conducting inspections of generators, transporters, and disposal facilities and will collect information on the number of inspections, number of violations, number of enforcement actions, number of penalties assessed and collected, and number of exception/discrepancy reports.

Regulatory Analysis

EPA has undertaken an on-going effort to evaluate the interim final regulation issued on March 24, 1989. Several parts of the rule (for instance, the definition of medical waste subject to the tracking requirements) are based on EPA's best technical judgment. EPA will consider whether the regulations should be clarified or otherwise modified during the life of the program.

Public comments were sought when the interim final rule was promulgated. Some of the comments may provide additional information and recommendations relevant to an evaluation of the demonstration program. In subsequent reports, EPA will evaluate these comments and other information and expert opinion on the extent to which of the regulations created a successful program.

Recreational and Occupational Injuries and Disease

The demonstration program has the potential to decrease recreational and occupational injuries. First, a larger quantity of medical waste will be packaged securely, reducing the chances that waste handlers and the public are exposed to medical waste. Second, the identification of medical waste (labels, marking tags, tracking form) should help deter the improper management of the waste and make it more likely that the waste will be handled with appropriate care. The analysis of public comments will allow EPA to determine if its interim final standards are adequately protective, and the analysis of compliance will indicate the extent to which exposure is actually reduced.

In addition, documentation from the analysis and information gathering process conducted by ATSDR under Section 11009 may provide relevant findings. For example, the information on the number of people injured by sharps and the nature of those injuries may suggest ways the demonstration program could be modified to reduce such injuries. In subsequent reports, these and other sources of information will be evaluated to determine improvements in public health protection due to the regulations.

Overall Medical Waste Management

There are certain limitations in evaluating the demonstration program against measures that involve the overall management of all medical wastes. For instance, the demonstration program only applies to certain medical wastes generated in Covered States; household waste is excluded; waste from illegal intravenous drug use is not addressed; and treatment/disposal practices and impacts (such as air emissions) are not covered under the authority of the program. Because "medical waste" as defined under RCRA excludes domestic sewage, the RCRA medical waste program does not require generators to track medical waste that is disposed to the sewer. As a result, the tracking program will not directly produce data on the quantity of medical waste discharged to the sewer or detect any shift to using the sewer for disposal. Generators of less than 50 pounds per month of regulated medical waste are exempted from the full tracking requirements. Chapter 11 describes in more detail issues and concerns regarding regulated medical waste from small quantity generators and households. Despite these constraints, it is still appropriate to consider the impact of the demonstration program generally on medical waste management, including beach wash-ups/closings and treatment/disposal practices.

Beach Wash-ups/Closings

This is an imprecise measure of success for the demonstration program, since not all the waste wash-up will be addressed within the scope of the demonstration program. However, one of the principal concerns behind the MWTA was the beach closings caused by the wash-up of medical waste. The Agency plans to take several actions to evaluate the impact of the demonstration program on beach wash-ups/closings.

- EPA will continue the beach wash-ups study started in 1988 for six states--Connecticut, Maryland, Massachusetts, New Jersey, New York, and Rhode Island. This study is an inventory which includes the following data: date of wash-up, state, beach location, and quantity and type of medical waste.
- The majority of the medical waste reported in the 1988 inventory is syringe-related waste. The Agency will in 1989 and 1990 analyze samples of the syringe-related wastes in order to attempt to determine their source. Possible sources include those covered under the demonstration program (hospitals, physicians, dentists, etc.) as well as sources outside the scope of the program (household use, intravenous drug use).
- Subsequent reports will also summarize other beach wash-up related studies that may be available.

The next interim report will include information from the 1989 summer beach season, while the final report will include studies from the 1990 season.

4.3 Conclusions on the Success of the Demonstration Program

In the next two reports, EPA will describe the success of the demonstration program in tracking and managing regulated medical waste, based on information available on state participation, compliance, regulatory analysis, recreational and occupational injuries, and beach wash-ups/closings.

EPA will assess the overall merits of the demonstration tracking system, in light of the shifts in monetary and nonmonetary costs to various affected groups, and its usefulness as a potential national program.

EPA will also assess other benefits of the program such as increases in public awareness, changes in perceptions of the health and safety risks of handling wastes or visiting the beach, and collection of information that will allow for a better understanding of the program. Because the demonstration program is only one of a number of laws enacted to address beach wash-ups, it is not entirely appropriate to judge the medical waste tracking program's success based on restored public confidence in beach-going. However, EPA will note well-documented changes in public risk perceptions for Congress' information, in future reports.

4.4 Treatment/Disposal Practices

Section 11008(a)(4)(B) requests information on changes in incineration and storage practices attributable to the demonstration program. These waste management changes may affect patterns of public and worker exposure to the waste. For instance, increased on-site incineration to avoid costs associated with tracking wastes shipped off-site, reduce exposures associated with waste pick-up and off-site handling, but result in greater exposure of patients and nearby residents to the incinerator emissions. The transporter and incinerator reports required by subsections §§259.62 and 259.78 will indicate some changes in incineration and other management methods during the demonstration program. In future reports, EPA will attempt to evaluate the relationships between these management changes and public/worker exposure.

4.5 Available Tracking Methods

Section 11008(a)(4)(C) requires EPA to report on other available methods for tracking medical waste. Currently, there exist a significant variety of shipment management systems that are being implemented by industry and commerce. The types of such systems range from the basic shipping paper and multiple-copy manifest systems to automated systems implementing bar codes and automated optical scanners to monitor and record transfer and movement of materials. Other divergent approaches exist as well; strict regulation of transporters, for example, is one potential solution to effective management of regulated wastes. The Agency has, in the past, implemented several tracking-type systems to assist in the implementation of its environmental regulations, and in selecting those methods has reviewed a range of alternative systems to those utilized. For tracking medical waste, EPA has developed and is implementing a system which will:

- effectively monitor regulated medical waste transactions;
- assure all parties involved of the waste's proper management; and
- meet all requirements set forth by Congress.

Current Practices

Medical waste shipments have been managed and tracked more recently using a variety of methods. The methods employed depend on the individual state and local regulations and the transporter involved in the movement of the material. The State of Illinois, for example, has regulated infectious wastes originating at hospitals as "Special Wastes" which require the use of a 6-part manifest and the submission of signed copies to the State regulatory agency. The States of New York and New Jersey have required the use of special 4-part manifest forms since their Emergency Rules went into effect in August of 1988; copies of the form are not sent to the states under this approach. The State of Pennsylvania is proposing to implement an 8-part tracking form utilizing the uniform Hazardous Waste Manifest. These state tracking requirements are discussed in more detail in Chapter 8.

Independent transporters have, in some instances, taken it upon themselves to implement various forms of medical waste tracking for a variety of reasons, including client reassurance, compliance with other States' regulations, attempts to reduce their potential liabilities, or simply to facilitate business transactions such as billing.

The Medical Waste Tracking System

The Agency has developed a medical waste tracking system for implementation in the demonstration program which is based upon a standardized multiple-copy manifest-type form. The tracking form is similar in format to the Federal Uniform Hazardous Waste Manifest (UHWM) required for the transport of hazardous wastes, and the medical waste manifest forms used by New York and New Jersey. It provides the necessary paper trail to document the transport and transfer of individual shipments of regulated medical waste from the point of generation to the designated point for treatment, destruction, or disposal, but the system does not require copies of the form to be sent to state regulatory agencies.

Alternative Tracking Systems

Currently, there are a range of other shipment management systems that are being implemented or in development. Systems range from the basic shipping paper for an individual package to advanced on-time surveillance techniques to trace the minute-by-minute movement of the vehicle and its contents. In general, the available and potentially-available systems applicable to medical waste tracking fall into three basic categories: (1) paper-based documentation; (2) computer-based documentation/tracking; and (3) real-time tracking systems. Additionally, in a more retrospective approach, there are several methods for tracing wastes once they have been mismanaged.

Paper-Based Systems

To date, EPA has relied on paper-based tracking systems. Paper-based documentation is the most prevalent method currently in use today in commerce and includes the employment of shipping papers, coupons, multiple-copy manifests, and tracking forms, among others. Generally, this type of system monitors shipments every time there is a transfer to another party. These systems have been developed and refined to suit the requirements of their intended applications:

> **Shipping papers** or bills of lading are commonly employed in the transport of commercial goods, including DOT-designated hazardous materials. Such forms serve multiple purposes by providing documentation of the material or goods being shipped, special handling information if required, destination information, and a record of receipt for the transporter when signed off by the receiving party; additionally, billing information may be included.
>
> **Coupon systems** are currently employed on the state and local levels for documenting municipal waste disposal. New Jersey has developed and implemented such a system; it enables the State to track the origin and volume of municipal waste, as well as its actual destination. The licensed hauler

completes one part of the state-provided coupon form with company identification and shipment origin information; a breakdown of the waste load by municipality and volume is completed on the reverse side of the coupon. Upon delivery to the disposal facility, the facility operator completes its section of the coupon, and retains that portion as a record. The hauler retains the other portion for its own recordkeeping. Other coupon systems are used on a smaller scale for recordkeeping and to facilitate charging for deliveries of municipal-type wastes to local landfills.

Multiple-copy manifests and tracking forms are currently in use on a broad scale. The Uniform Hazardous Waste Manifest (UHWM) system for hazardous waste shipments has been in place since 1984. It incorporates a four-part minimum form which provides all parties that handle a hazardous waste shipment with a copy for their records, with an additional copy for the receiving facility to send back to the original generator upon receipt of the shipment. An integral part of the UHWM system is the requirement for discrepancy reporting by facilities, recordkeeping, and exception reporting (reports of "stray" shipments) by generators. The multiple-copy system produces a well-documented paper trail (chain-of-custody) which allows an individual waste shipment to be tracked from its site of generation to its destination.

Pre-notification systems are based on the premise that an anticipated shipment that does not arrive is suspect, and is investigated by the receiving facility. In theory, actual tracing of individual shipments need only be carried out for those shipments, and not for all other scheduled deliveries that arrive intact and on-time. Currently, EPA's Office of Toxic Substances is proposing a manifest system for polychlorinated biphenyls (PCBs) which incorporates a pre-notification procedure. Under the proposed system, generators intending to ship PCBs are required to submit an advance notification to the destination facility that a PCB shipment is scheduled. A copy of the corresponding manifest form must be forwarded as well. This action alerts the receiving facility to prepare for the shipment's arrival and to initiate investigation if the shipment does not reach the facility within the allotted time period. Similarly, utilities intending to ship spent nuclear fuel for long-term storage must complete a multi-step advance notification process for their shipments.[3]

Computerized Documentation/Tracking

The advent and prevalence of computer technology has provided the opportunity for development of computer-based tracking systems. Proprietary automated computer manifesting, tracking and report systems for shipment of hazardous waste and low-level nuclear materials for generators, transporters, and receivers of such materials have been developed. As updated information is entered by each party handling a shipment, a centralized computer system can generate manifests, maintain manifest information and track progress of shipments. Some of these systems can be programmed to submit reports automatically to regulatory agencies.

Other types of available computer-driven systems rely on the use of bar coding and optical scanning equipment. Currently, such technology is used by industry in a quality control capacity. Producers of health care products may identify their products by product number, lot number, and production date through the use of bar codes and use optical scanners to record product information throughout the numerous manufacturing and handling stages. Combined with centralized computer systems, these systems facilitate the management of inventory and shipment information and enable the producers to remove expired or recalled stock. These computerized methods have application to the management and control of medical waste shipments through centralized tracking of individual packages. For example, one company has had a similar system in-place for the past two years which records shipment information for its medical waste transport activities.[4] The system uses a combination of bar code labels and optical scanners and is supported by personal computers.

Real-Time Tracking Systems

Another advancing concept currently employed is that of "real-time" management. Real-time information can provide the user with an up-to-the-minute monitoring and status reports of the subject of interest, whether it is a package or an entire vehicle. This system allows constant surveillance. Overnight delivery services implement advanced, state-of-the-art systems like this to manage, track and trace individual parcels across the U.S. and elsewhere. These systems combine time-saving equipment such as bar code readers with portable data collection unit, and on-board computer/transmitters, configured to send shipment data to a collection and processing point and a centralized computer system. The system can trace an individual package at any point along its route and verify its delivery to the designated address. Inventory, time-tracing, lost parcels, and invoicing are all greatly facilitated by this system. Such systems have been considered as a realistic option to provide real-time data systems for the movement of radioactive wastes. In addition to computer-based systems, the plausibility of employing satellite surveillance of high-risk shipments is also being investigated.[3]

On a smaller scale, a similar system has been installed by one blood supplier for tracking donor blood throughout its product life. Blood bags that have been distributed that were provided by a disqualified donor can quickly be removed from circulation before they are utilized.

Tracing

While medical waste tracking systems may be necessary to ensure the appropriate management and disposal of such material and to provide a reliable record of these transactions, there are a variety of "after the fact" waste tracing techniques which, in combination with tracking, may assist in the enforcement of medical waste regulations. Such techniques may also deter others from mismanaging these materials.

Floatable identification tags are required by the State of New York to be included by the generator in each bag of infectious waste it disposes off-site.[6] If the material is improperly disposed on land or in the water, the tags assist the investigator in identifying the source of the waste.

Confetti-style identification tags have been proposed as a method for identifying parties responsible for mismanaged medical waste. This technique involves the inclusion of multiple, small identification tags in each package of medical waste to be disposed of off-site. If the tags are found in mismanaged waste or washed up on a beach, an investigation can be initiated. The number and small size of the tags could deter anyone from attempting to remove them prior to improper disposal.[7]

Micro-coded particles have been developed which can be used to mark materials or individual items for positive product identification. One product utilizes combinations of unique color-coding schemes which are then assigned to each individual source. The smaller sized particles can be spray-applicated to mark products subject to theft and are included in commercial explosives to allow tracing of their illegal use by identification of manufacturer, lot, batch, type, etc.[8] Such a system may be applicable to medical waste either by including coded particles in each package or spraying the liquid form. An investigator could identify the source of whole packages or individual items such as syringes that would not be traceable otherwise.

Product coding/recordkeeping using ink-jet coding of products with alphanumeric or bar codes during manufacturing may be used to trace sources of mismanaged medical waste. Currently, such coding has been used on consumer products ranging from beer cans to non-prescription drugs, primarily for inventory and quality control. Use of such coding schemes by manufacturers could allow the tracking of a product from its point of generation or production through to disposal. Very sophisticated recordkeeping processes would be required to implement this system.

4.6 Advantages/Disadvantages

This section briefly describes some of the advantages and disadvantages of the various tracking approaches that have been described above.

Paper-based systems have been the standard by which most commodities and other regulated materials are managed and tracked in transit. Advantages for these, other than their prevalence, are the relative low implementation and maintenance cost, simplicity in use, and, for multiple-copy forms, the existence of a copy for recordkeeping. Disadvantages vary with the specific systems but generally include the susceptibility to human error either in completion or in handling; furthermore, record maintenance and data summaries are labor intensive and time-consuming. Pre-notification may require the provision of additional forms which must be handled and processed. Six or eight-part manifest forms which provide copies for submission to regulatory agencies can require a time-consuming, labor intensive process to match up corresponding copies. Other, simpler paper-based tracking approaches such as the basic shipping paper may not provide the necessary control for high-risk material shipments.

Computer-based tracking systems are less well-characterized since they have only recently been implemented to any significant degree in a regulatory capacity. Advantages include a potential reduction of human error, both in data input and direction of shipments and corresponding documentation. These methods can save time and reduce the labor required for processing status reports and recordkeeping. Disadvantages include the significant start-up, as well as maintenance costs for advanced systems, the significant training of personnel to use these systems, and the potential for breakdown and resulting "down" time.

Real-time systems, which are a subset of the computer-based systems, have similar strengths, and may provide excellent shipment monitoring and tracking of individual packages or entire shipments, with the capability for immediate tracing when necessary. These systems can provide the user and the regulatory official with immediate status reports of shipments and can save time if corrective or enforcement action becomes necessary. In addition to the disadvantages cited for the computer-based systems, the real-time concept requires a high degree of cooperative effort and extensive implementation to operate effectively.

Tracking System Evaluation

The Agency has historically relied on paper-based tracking and tracing for regulation of materials transportation. The record of these efforts has been documented. During the demonstration program, EPA will evaluate the effectiveness of the medical waste tracking form system to monitor regulated medical wastes adequately from their point of generation to their destination. During this evaluation process, there will be sufficient time to examine other available alternatives for tracking medical waste more thoroughly. EPA will evaluate the potential success each system would have in tracking regulated medical waste; EPA will also assess the systems' use in rural areas, and use by small quantity generators as required under 11008(a)(4)(C).

The Agency evaluation will be organized as follows:

Systems identification will continue so that we can evaluate a comprehensive set of systems with potential application to the management of medical waste. Currently, the more prevalent or better advertised systems are known to the Agency; other systems may exist and need to be identified and reviewed.

Information collection will be instituted to create an adequate base on which to evaluate each of the systems. Contact with users and designers of the systems will provide an additional valuable source of this data.

Development of evaluation methods will determine the criteria to measure and rate the systems. Presently, a number of criteria are considered crucial to the analysis:

COST: The projected cost of each system, both in terms of implementation costs, start-up costs and maintenance costs, is a significant issue. The evaluation will attempt to identify all direct and indirect costs associated with each alternative system to understand the potential cost-effectiveness of each. Other criteria described below are directly tied to the issue of costs.

IMPLEMENTATION: The ease and speed of implementation of each tracking system is of significant importance. New methods and different technologies will necessitate greater effort and time than those methods that are currently in use. Tracking regulated medical waste can only be effective if the system is operating efficiently.

LEVEL OF EFFORT: The level of effort necessary to implement and maintain a tracking system is directly tied to the issue of cost. More complex and labor-intensive systems will require added degrees of manpower and time, which will be directly reflected in the associated costs.

SKILL/TRAINING REQUIREMENTS: Each system will be evaluated on the basis of the level of special skill or training that individuals will require in their day-to-day operations. The more basic and familiar systems will necessarily require less specialized skills. In addition to affecting the regulated community, the individual tracking system will impose varying degrees of specialized skill requirements for regulators monitoring and enforcing the medical waste program.

ENFORCEMENT: The nature and basis of each alternative tracking system will directly affect its enforceability by the Agency and other regulatory agencies. Effectiveness of a tracking program will be directly related to the actual or perceived extent of enforcement against illegal activities. Therefore, the Agency will evaluate each by an appraisal of the regulatory community's capability to monitor and respond to prohibited activities involving regulated medical wastes.

EFFECTIVENESS: The Agency will proceed with a comprehensive analysis and projection of the potential effectiveness each system would have if implemented for the tracking of regulated medical waste. EPA will use the information concerning past and current experience with the tracking systems implemented to date.

The criteria, as developed, will be applied equally to all identified tracking methods to identify the relative advantages and disadvantages of each.

The comprehensive evaluation of tracking systems will require a thorough analysis of the medical waste tracking system that has been developed and implemented in the demonstration program. The demonstration program will provide an opportunity to analyze the tracking system's effectiveness in both rural and urban settings and to analyze the effects of including small quantity generators in the tracking system. The format of the analysis and evaluation will include a comparison of the relative advantages and disadvantages of each identified tracking system.

4.6 References

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CHAPTER 5

MEDICAL WASTE HANDLING METHODS

5.1 Introduction

Section 11008 (a)(5) of RCRA as amended by the Medical Waste Tracking Act (MWTA) of 1988 requires that EPA describe the available and potentially available methods for handling, storing, transporting, and disposing of medical waste and the advantages and disadvantages of these methods. This chapter addresses packaging, which includes labeling and marking; on-site storage; off-site transportation; and disposal to landfills, sanitary sewers and the ocean. (Treatment of medical waste is discussed in the following chapter.) The term "handling" will be used to describe generically any or all of these practices.

Section 5.2 describes current handling practices likely to be in use in states not participating in the demonstration program. Some of this information is based on site visits in New York and New Jersey before the 40 CFR Part 259 regulations were promulgated. Sections 5.3 - 5.5 describe the standards implemented in the rule, emerging or alternative handling techniques, and potential methods for evaluating medical waste handling practices.

5.2 Current Practices

Handling and Packaging Practices

Medical waste handling methods, e.g., packaging, depend largely upon the disposal method or location of the disposal facility, and the existence or lack of state and local regulations. This section describes the handling methods that are currently used to prepare medical waste for transport off-site for incineration, transport off site for land disposal, disposal or incineration on site, sewer disposal, and ocean disposal.

For Off-Site Incineration

Medical wastes destined for incineration off-site, excluding sharps and fluids, are generally packaged in plastic bags at the point of generation. These bags are either red in color or labeled with a biohazard symbol for identification. The waste may be single- or double-bagged. The weight of the waste often determines whether one or two bags are used.[1]

Waste that is transported by commercial haulers is usually consolidated and prepared for off-site transport in cardboard boxes and/or in reuseable bins, drums, etc. Vehicles used to haul the waste may or may not be compactor trucks, depending on existing state or local regulations. In addition, secondary containers or additional packaging may be required by state or local regulations, or by the disposal facility. Waste transported by the generator is not always as carefully packaged and may not be placed in a secondary container.[2,3] Medical waste generated in laboratories is typically autoclaved prior to packaging and transport off site to an incinerator.

Medical waste is sometimes compacted prior to packaging or transport. A survey conducted in King County, Washington found that 31% of the hospitals surveyed compacted sharps and liquid wastes. Other generators (medical offices, laboratories, and veterinary offices) did not compact sharps or liquid wastes.[4]

Sharps, such as needles, scalpels and syringes, which may pose a threat to worker safety, are commonly contained in rigid, puncture-resistant sharps containers as the primary packaging. The majority of hospitals and other medical facilities use such sharps containers.[5,6] The practice of clipping the sharps for disposal has become less common because of the risk of needle stick injuries.[7] Other types of glassware are typically placed into plastic bags which are then placed into rigid cardboard containers or reusable drums or bins.

Liquids that are not sewered are commonly contained in rigid, break-resistant containers. Some suctioned fluids are suctioned directly into rigid plastic disposable containers. Small quantities of liquids from lab specimens (such as blood vials) are often poured directly into plastic bag(s) and then placed in a box or other container.[8]

For Landfill Disposal

The majority of medical waste is transported off-site for disposal in municipal landfills. The waste is typically packaged in plastic bags and handled as general municipal solid waste (placed in a dumpster until transport and sometimes compacted). In states or localities where only treated medical waste can be landfilled, the regulations usually specify a method such as steam sterilization. This waste, destined for landfill disposal, is often packaged on site in autoclavable (e.g., polypropylene) bags, decontaminated, and then handled as general solid waste.

For On-Site Treatment or Disposal

Facilities with on-site treatment and disposal capabilities, e.g., incinerators, are primarily concerned with packaging medical waste to ensure worker safety. Single or double red bags are often used; however, less care is taken to segregate medical wastes from other wastes. The medical waste is rarely placed in secondary containers or marked, and is often moved about the facility in open carts.

For Sewer and Ocean Disposal

EPA considers sanitary waste that passes through a sewer system to be "domestic sewage," which is excluded from the definition of solid waste under RCRA Section 1004(27). In addition, EPA interprets the domestic sewage exclusion to include mixtures of sanitary wastes and other wastes that pass through a sewer system leading to a publicly owned treatment works for treatment [see 45 FR 33097, May 19, 1980]. Such mixtures are not "solid waste," and thus are not "medical waste" under RCRA once they enter the sewer system that will mix them with sanitary wastes prior to storage or treatment by a publicly owned treatment works. Some body fluids resulting from medical procedures such as surgery, or from autopsy, are suctioned and discharged directly into the sewer system.[9] Others are placed in temporary holding containers and then poured into the sewer system. Recent amendments to the Federal Water Pollution Control Act (contained in Public Law 100-688) may affect these practices; in addition, state or local requirements may also affect these practices.

Ocean disposal of medical waste is prohibited or restricted as a result of the United States Public Vessel Medical Waste Anti-Dumping Act of 1988, the Marine Protection, Research and Sanctuaries Act of 1972, and the Act to Prevent Pollution from Ships. The U.S. Navy has altered handling practices and is presently evaluating methods that treat, compact, package and store ship-generated medical waste on board, or that treat and destroy medical waste, thereby allowing its disposal at sea.

Storage

Medical waste that is transported off-site for disposal may be stored in indoor or outdoor storage areas. The location and capacity of a storage area depends on the quantity of medical waste generated, the frequency of pick-ups, urban versus rural location, and whether on site or off site disposal will occur. Facilities that generate large volumes of waste and/or are located in urban areas often store the waste inside and have frequent pick ups due to limited storage capacity. A facility with fewer pick-ups may prefer to store the waste outdoors for aesthetic reasons. Storage time can vary from less than 6 hours to one month, or "as needed."[10]

Medical waste intended for on-site treatment (e.g., incinerator) is generally stored in rooms near the incineration facility. Outdoor storage is less common, except where space may be a problem. In a small, rural hospital, for example, storage may be more convenient outside even if the waste must be brought inside again for treatment. Some storage areas have a lock and/or limited access.[11,12]

In general, wastes that may become putrescent quickly (e.g., bulk pathological wastes) are stored in refrigeration units until transport or treatment.[13]

Transport

Trucks are the most common type of vehicle used to pick up and transport medical waste. New York's municipal solid waste is sometimes transported by barge. Small vehicles similar to vans are used to pick up small quantities of medical waste from individual practitioners. Dump trucks are sometimes used in rural areas. Flat-bed trucks are also used when the waste is stored in large containers (roll on - roll off) which can be removed from the facility for transport to a disposal facility. Compactor trucks are used when landfills allow such disposal. When medical wastes are hauled long distances to disposal sites, tractor trailers are often used. Some haulers also employ refrigerated trucks for transport; however, this is not an industry-wide practice. EPA does not believe rail transport is used for medical waste transportation except when such waste is included in municipal solid waste. One railroad presently moves some municipal solid waste from East Coast states to the Midwest for disposal.[14]

Commercial transporters are commonly used to haul medical waste off site for incineration (or for other disposal in addition to landfilling). Commercial transporters are especially popular in urban areas where they can make several pick-ups in a small area.[15]

The practice of shipments of sharps via the U.S. Postal Service and specialized sharps transporters has been growing and is gaining in popularity for generators of small quantities of sharps. With respect to the specialized transporters, the generator is typically supplied with containers in which the sharps can be packaged for transport to a final disposal location. These transporters typically serve small generators (e.g., nursing homes and physicians) although the practice is expanding to larger generators such as hospitals.[16,17] In New Jersey, a pharmacy that supplies pharmaceuticals and sharps to nursing homes has engaged in collecting and transporting the used sharps for disposal.[18]

Generators of small quantities of waste or generators in rural areas are more likely to transport waste to the disposal facility themselves. Generators of small amounts of medical waste, e.g., individual practitioners, often transport the waste to a larger generator (a hospital or laboratory) who in turn disposes of or arranges for the disposal of the waste.[19]

Landfill Disposal

Most medical waste that is not incinerated, and ash from incineration, is disposed in landfills. While infectious medical waste is often treated (steam sterilized) prior to landfilling, depending on state and local regulations, several types of generators dispose of small quantities of untreated medical waste directly in landfills.[20]

A landfill operator's self-imposed restrictions may also determine what is disposed of and how the waste is handled. For example, landfills serving urban areas sometimes do not accept certain wastes from medical waste generators, even though they are allowed to under existing state or local laws.[21] Where capacity is less of a problem, e.g., in rural areas, there are generally more liberal policies about accepting waste. The controls that the landfill places on medical waste directly affect generators, and cause them to adapt to the standards set by the landfill operator.

5.3 Standards Implemented by the Rule

The regulations, promulgated at 40 CFR Part 259, address current required handling methods of medical waste through standards for segregating, packaging, storing, labeling, marking, and transport of the waste.

Segregation

Section 259.40 requires generators to segregate sharps, (including sharps containing residual fluids) and fluids (in quantities greater than 20 cubic centimeters), from other regulated medical waste to the "extent practicable" if the waste is intended for off-site transport and disposal.

Packaging

The packaging requirements are designed to protect waste handlers and the public from exposure to regulated medical waste. General requirements for packaging regulated medical waste have been established in 40 CFR 259.41. Prior to off-site transport, regulated medical waste that is not "oversized" must be packaged in rigid and leak-resistant containers that are impervious to moisture, sufficiently strong to prevent tearing or bursting under normal handling, and sealed to prevent leakage during shipment.

Sharps must be packaged in containers that meet the above requirements, and that are puncture-resistant as well. Fluids in quantities greater than 20 cubic centimeters must be packaged in containers that meet the above requirements, and are also break-resistant and tightly lidded or stoppered. Reusable containers are permissible; in many cases, containers that can be loaded on pallets and mechanically moved can be used, as long as the containers are not subjected to undue stress or compaction during transport, loading and unloading.

While EPA did not establish specific requirements for oversized medical waste, EPA recommends that these wastes should be managed in a manner that protects the handler and the public from exposure.

Labeling

Section 259.44 requires generators to label packages containing untreated regulated medical waste with the words "infectious waste" or "medical waste," or with the universal biohazard symbol. Each layer of packaging or container used to meet the packaging requirements must be so labeled. Treated medical waste does not require a label on the package.

Marking

The outer surface of all regulated medical waste containers that are used to meet the packaging requirements must be marked to identify the generator, if the waste is transported off-site. The outermost surface of the outermost container must also identify the transporter(s) and the date of shipment. The markings must be water resistant. Other markings such as bar codes are also allowed. Markings are required by Section 259.45 to help identify those persons responsible when waste that has been mismanaged or improperly disposed is found.

Storage

Medical waste stored on site prior to off-site transport or on-site treatment or disposal must be (1) stored in a manner and location that protects the integrity of the packaging; (2) afforded protection from water, rain and wind; (3) maintained in a non-putrescent state; (4) stored with access limited to authorized employees; and (5) protected from animals. If stored in outside storage areas, the regulated medical waste must be in units such as dumpsters, sheds, and tractor trailers that are locked to prevent unauthorized access.

Transport

Section 259.73 specifies that regulated medical waste must be transported in a leak-resistant, fully enclosed, cargo-carrying body that is maintained in good sanitary condition. Compaction of packaged waste must be avoided because it can destroy the packaging, markings, and labels and increase the potential of exposure to handlers or the public from regulated medical waste.

5.4 Evolving Handling and Management Techniques

Handling

Sharps

A variety of new types of containers are being developed in which sharps can be directly placed and contained for shipment. These include both fiberboard boxes and plastic containers. The advantages of these types of containers is that they can be closed, limiting exposure in the event of mishandling, and are rigid and leak- and puncture-resistant. Other management and/or containment systems will be addressed in the next interim report that could minimize the handling of bags and other containers by healthcare workers and waste handlers.

Marking

Evolving methods of marking medical waste to identify its source include the use of bar codes and optical scanning equipment or readers. Bar code systems (discussed in greater detail in Chapter 4) are useful only to individuals capable of decoding the information; otherwise, they are not an effective method of identifying the generator or transporter of waste. New York has required generators to place floatable tags in each package of waste in order to identify the generator of the waste washed up on a beach. Other tracing or detection methods with potential application include confetti sized markers or tags or micro coated particles, as discussed previously in Chapter 4.

Compaction

Compaction of medical waste during or prior to packaging is discussed in Chapters 6 and 7 because it is a method that reduces the waste's volume. The regulations at 40 CFR 259.73 prohibit compaction of containers of regulated medical waste during loading onto a transport vehicle, during transit, and during unloading. However, systems exist within hospitals in which unpackaged and/or untreated medical waste is being compacted into bulk containers prior to transport off site. Some of the systems in use are capable of loading compacted waste in bags into a dumpster, incinerator or truck without direct handling of the bags. However, potential problems for the haulers and destination facilities may exist when the bags are unloaded from a truck during final disposal.

The Department of Defense (DOD) is presently evaluating various treatment and compaction options to contain and store medical waste while vessels are at sea. Compaction could be beneficial in urban areas where both storage space and disposal location are problems; however, EPA believes that certain untreated medical wastes should only be compacted if the compaction takes place in a closed chamber which eliminates the possibility of exposure to infectious agents through aerosols.

Transport

Systems are evolving which minimize handling of regulated medical waste by the healthcare worker and waste handler. Automated systems are available that will treat, compact, and package waste placing it directly in bins that can be mechanically loaded and unloaded, thus avoiding direct handling by the healthcare worker. System applicability depends on the amount of waste generated, existing management techniques and their acceptance, and the facility's ability to meet new capital and operational and maintenance costs.

Rail shipment may be evolving as an alternative to transport by truck. Although EPA cannot cite a specific instance of the transport of medical waste by rail, one rail company is presently moving municipal solid waste to midwestern States for disposal[22]. Intermediate length truck hauls (400 to 600 miles) of medical waste are occurring from sites of generation in New York and New Jersey to disposal facilities in Ohio, Quebec, and South Carolina. The economic viability for intermodal truck-rail transport may soon be present. Roll-on/roll-off containers and trailers on flat cars may be viable future transport options.

Due to the shortage of landfill capacity within the State of New Jersey, some municipalities are compacting municipal solid waste at bale and transfer stations and are shipping it to out of state landfills.[23] A similar system could be implemented for medical waste. If medical waste destined for a landfill has been properly treated, the potential threat posed by exposure to pathogens through compaction may be reduced. However, the physical danger from sharps, which results when bags and boxes are crushed from compaction, is still present.

5.5 Methods to Evaluate Medical Waste Handling

The effectiveness of alternative medical waste handling practices can be evaluated on the basis of several factors including cost, operational ease, reliability and the reduction of potential hazards. A variety of measures could be considered by the health care industry and waste management industry to evaluate the available and potentially available handling and management method, as follows:

- Capital cost for purchase of handling system
- Operational and maintenance costs

- Time required to implement each handling system, including necessary training
- System integrity and reliability
- Likelihood of self-implementation
- Effectiveness in reducing worker exposure to the waste, and
- Effectiveness in reducing the public's exposure.

In future reports, EPA plans to evaluate the alternative handling methods presented in this chapter, using the last two measures.

5.6 References

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CHAPTER 6

MEDICAL WASTE TREATMENT METHODS

Section 11008(a)(6) requires EPA to report on available and potentially available methods for treating medical waste. There are a variety of available methods for treatment of medical waste to render the waste noninfectious or less infectious, and unrecognizable. In accordance with the breadth of processes specified in 11008(a)(6), the term "treatment", as used in this and the following chapter, includes processes that cause waste to become less recognizable. This usage is thus broader than the definition of treatment found at 40 CFR 259.10(a), which limits treatment methods to those

> ...designed to change the biological character or composition of any regulated medical waste so as to reduce or eliminate its potential for causing disease.

The principal available and potentially available techniques for treating medical wastes are:

- Incineration
- Steam Sterilization
- Gas Sterilization
- Chemical Disinfection with Grinding
- Thermal Inactivation
- Irradiation
- Microwave Treatment
- Grinding and Shredding
- Compaction

The following sections describe each method and discuss the advantages and disadvantages of each. At this point it is not possible to estimate the proportions of Section 11002 waste types that are subjected to each treatment technique, or to various combinations of treatment techniques. Some of this information may become available as the incinerator and transporter reports required by 40 CFR 259.78 and §259.62 are submitted; if it does, EPA will provide it in future reports. In addition, further information on the treatment processes described here and others (such as chemical disinfection) will be provided in future reports.

6.1 Incineration

Incineration is a process in which wastes are burned under controlled conditions to oxidize the carbon and hydrogen present in the waste. Incineration can be used to treat many types of waste; materials which are not incinerable remain as residue, along with unburned combustibles.

Three principal categories of medical waste incinerators are used in the U.S. These classes are:

- Modular, starved air incinerators
- Rotary kilns
- Retort or batch incinerators

Rotary Kilns

The rotary kilns consist of a large metal drum lined with ceramic bricks. The kiln is tilted at a slight angle and is slowly rotated. The waste is introduced at the upper end and moves slowly through the device. The kiln rotation is a means to mix or stir the burning bed and transports the solids through the kiln. Auxiliary fuel and air are sometimes used to aid in the destruction of organic material. The amount of auxiliary fuel used depends on the desired temperature, the quantity of air introduced and the heat content of the waste. The waste material burns as it moves through the kiln and residual ash is continuously removed from the lower end.

The gases formed by the burned waste move from the kiln into a stationary chamber called a secondary chamber. More air and fuel are added to aid in the destruction of the organic compounds in the gas. Typically the kiln is operated at around 1600°F and the secondary chamber around 2000°F. The gases leaving the secondary chamber enter the heat recovery and air pollution control equipment, if the incinerator is equipped with these devices. Otherwise, the gases leaving the secondary chamber are emitted to the atmosphere.

Modular, Starved Air Incinerators

In this type of system, wastes are pushed through the primary combustion chamber in new facilities by compressor rams, and loaded manually in older facilities. Air is blown up through the waste from below. The devices are known as starved air incinerators because controlled (substoichiometric) quantities of air are introduced into the primary chamber to partially burn the organic material. The partially burned organic compounds are discharged (leave) the primary chamber and enter into the secondary combustion chamber.

The exhaust gases flow from the primary chamber into the secondary chamber where additional air is added. Often auxiliary fuel is added to aid in the complete destruction of all of the unburned material in the gas. As in a rotary kiln, the gases leaving a modular starved air incinerator may pass through heat recovery equipment and/or air cleaning equipment, or may be emitted directly into the atmosphere. This type of incinerator has uncontrolled particulate emission levels of about 0.1 grams per day, standard cubic feet, if the unit is well-designed, well-operated, and well-controlled.

Retort or Batch Incinerators

Retort incinerators are the simplest type of incinerator. The operator preheats the waste burning chamber and places the waste inside. Preheating is not always conducted, but is recommended. Retort incinerators which are filled full of waste (i.e., "stuff-and-burn") cannot be preheated; but they may be designed to allow preheating of the after burner chamber. Fuel and air are introduced through burners. The incinerator operates until all the waste is burned; after a cool-down period, it is opened and the ash is quenched and removed. These incinerators could also be equipped with heat recovery and are rarely controlled by add on air pollution control equipment.

Advantages

Incinerators can potentially destroy any material containing organic carbon, including pathogens found in medical wastes. Incinerators typically reduce the volume and mass of material that must be disposed of in landfills by 80 to 95 percent. In addition, materials are less recognizable after incineration.

The heat from incineration can be recovered and used to generate steam, which can be used directly or can be used to generate electricity. Heat recovery devices reduce the net operating cost of the incinerator by creating a useful product.

Disadvantages

Air emissions from incinerators contain several pollutants of concern and is one of the principal disadvantages of using incinerators. In addition, incinerators are complex and require trained operators. The trend toward more stringent regulations will increase the complexity of incineration equipment. Rotary kiln incinerators have a number of moving parts, and thus may require more extensive maintenance than other techniques. Incinerators also represent a moderate risk to operators and maintenance personnel due to the high operating temperatures and the potential for fires. It is difficult to routinely test the ability of an incinerator to destroy pathogens. Medical waste incinerator ash may be a hazardous waste under RCRA Subtitle C regulations. This issue was previously addressed in Chapter 2, above.

6.2 Steam Sterilization

Steam sterilization, also known as autoclaving, is a commonly used method for decontaminating wastes. The term "sterilization" can be misleading in that waste is not actually sterilized in all cases. However, the term "steam sterilization" is commonly used because the same process is used for sterilizing equipment.

The waste is placed in a sealed chamber and exposed to steam at the required temperature and pressure for a specified time. The conditions commonly recommended for hospital sterilization are processing for 12 minutes in contact with saturated steam at 121°C.[1]

Advantages

The equipment used in steam sterilization is simple to operate. The technology is proven and has been used for many years in the health care industry. Steam sterilization is capable of decontaminating most medical wastes classes. It does reduce the volume and render some plastic materials non-recognizable. Additionally, there are biological indicators currently available which provide quality assurance for equipment friction.

Disadvantages

The process does not reduce the mass of material that must be disposed of after treatment. The steam sterilization process can produce extremely offensive odors. If odors are released, then volatile organic compounds may also be released into the ambient air. The odorous material could include toxic emissions. Also, steam sterilization does not affect the recognizability of most non-plastic wastes. Operators must be alert for wastes that can be volatilized by the high temperatures; in addition, a potential safety hazard exists because of the hot surfaces in the autoclave.

6.3 Gas Sterilization

In gas sterilization processes, waste is exposed to a gas. The wastes are placed in an air tight chamber; air is evacuated and a sterilizing agent, such as ethylene oxide or formaldehyde, is introduced. The gas penetrates the waste and kills infectious agents. Gas sterilization is rarely used[1] to treat medical wastes.

Advantages

Gas sterilization can be used to treat reusable items that cannot be subjected to heat and moisture.

Disadvantages

The use of gas sterilization is complicated by the potential worker exposure to the disinfectant gas, because ethylene oxide and formaldehyde are probable human carcinogens.[3] In addition, gas sterilization does not reduce waste volume or waste weight, nor does it affect waste recognizability. In gas sterilization processes, the toxic gases are vented to the atmosphere after use; treated materials contain residues of the sterilizing agent that are released over time.

6.4 Chemical Disinfection With Grinding

Chemical disinfection processes involve contacting medical wastes with a liquid chemical disinfectant. The wastes are initially ground to ensure that the chemical agent can penetrate the wastes and to aid in disposal of the residues. The materials then enter a bath where they are mixed with the disinfectant.

The resulting liquids, including any remaining disinfecting agents, are released to the sewer system while the solid residues are drained of the disinfectant and disposed of in a landfill.

Public Law 100-688, Title III, Subtitle B, §3202, adopted by Congress on October 19, 1988, forbids the discharge of medical wastes to navigable waters. EPA is considering the need to develop regulations to implement that prohibition. The Agency is concerned that certain pathogens may remain infectious even after they pass through a sewage treatment plant. Dischargers should not dispose of any medical wastes to the sewer without first checking with public health and municipal sewage treatment authorities to determine whether the disposal presents any risk to the public.

Advantages

The grinding will reduce the volume of the waste but will not reduce the mass. Wastes are generally rendered unrecognizable by the process, if the grinding results in a finely divided residue.

Disadvantages

The chemicals used as disinfectants may present a moderate risk to operators and maintenance personnel. Depending on the disinfectant used, the spent disinfectant solution may exhibit characteristics which make it unsuitable for disposal in municipal sewage systems. In addition, the ability of the process to render the waste less infectious has not been thoroughly evaluated.

6.5 Thermal Inactivation

Thermal inactivation involves heating a waste to temperatures which destroy infectious agents. Generally this method is used only for large volumes of liquid wastes.[4] Typically, the liquid wastes are placed in a chamber which is heated to a pre-determined temperature. The wastes are held in the chamber for a specified period of time and then released. Non-liquid wastes may be subjected to dry heat in an oven.

Advantages

Thermal inactivation can be used for liquids, which are not effectively treated by either steam or gas sterilization. The treated liquid waste can be discharged into a municipal sewer system.

Disadvantages

The extensive time and energy requirements preclude common use for treatment of waste in solid form.[5] Thermal inactivation does not alter the physical form or quantity of waste that must be disposed of after treatment. Federal, state, or local requirements for discharge to a sewer system may include a maximum temperature limitation; thus, heat exchangers may be needed to reduce a treated liquid waste's temperature.

6.6 Irradiation

Irradiation with ultraviolet or ionizing radiation is a potentially available method for treating medical wastes. The process involves using ionizing radiation from a source such as cobalt 60, to destroy infectious agents, or using ultraviolet radiation. Ionizing radiation techniques are similar to those currently being used to sterilize medical supplies, food, and other consumer products.

Advantages

Ionizing radiation has demonstrated two advantages over conventional treatment techniques: little energy input is required, because the equipment requires only a small amount of electricity and no heat, and it is suitable for use on materials which cannot be thermally treated.

Disadvantages

Ionizing radiation technology is complex and requires highly trained operating and support personnel. The radiation source in the device will eventually decay and require replacement. Disposal of the decayed source is a significant problem. The ability of source to activate trace metals present in the waste has not been well characterized.

Human exposure to ultraviolet radiation can cause adverse health effects.

6.7 Microwave Treatment

Microwaves are being used to treat medical wastes, although the technology has not yet been applied commercially in the United States. Using this technique, wastes are first ground and shredded to improve the effectiveness of the treatment system. Next the wastes are sprayed with water. An auger moves the wastes past a series of microwave power packs which subject the waste to microwaves. The microwaves heat the waste to 200°F, and volatile materials and water are driven off during the process.

Advantages

The grinding reduces the volume and recognizability of waste to be treated by as much as 80 percent. However, the weight is essentially unaffected. Portable microwave treatment facilities are commercially available.

Disadvantages

The main disadvantage of microwave treatment systems is that they are not capable of treating pathological wastes such as body parts or animal carcasses. Also, the potential for the release of volatile material may exist.

6.8 Grinding and Shredding

Grinding and shredding are used to convert medical wastes into a more homogeneous form that can be easily handled. In these processes, medical wastes are physically broken into smaller particles. The equipment is sometimes maintained at a negative pressure to ensure that no material escapes from the device. Needle-clipping devices are sometimes used to remove needles from syringes.

Advantages

Grinding will reduce the volume of the waste material. In addition, the processes may render the waste partially unrecognizable.

Disadvantages

There may be some health risk associated with operation of the equipment, because there is a potential for pathogens to form an aerosol as a result of the grinding and shredding process.

6.9 Compaction

Compaction techniques are used to reduce waste volume; they can also affect waste recognizability. A hydraulic ram is generally used to compress the waste against a rigid surface. It is not a technique designed to render a medical waste non-infectious or less infectious.

Advantages

Compaction reduces waste volume; it can render waste less recognizable to varying degrees.

Disadvantages

Compaction can destroy the integrity of containers, causing dispersion of materials. There is a potential for aerosols to form and be released; also, liquids can drain out of the device.

6.10 References

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4. U.S. Environmental Protection Agency, Office of Solid Waste. *EPA Guide for Infectious Waste Management.* EPA/530-SW-86-014, May 1986.

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CHAPTER 7

MEDICAL WASTE TREATMENT EFFECTIVENESS

For each of the treatment methods identified in Chapter 6, operating procedures can affect the method's effectiveness in reducing the waste's disease-causing potential, or in rendering the waste less recognizable. As required under 11008(a)(7) this chapter outlines the effectiveness, including operating factors affecting effectiveness, available quality assurance procedures, required maintenance, and operator training requirements of the methods identified in the previous chapter. In future reports, EPA will further develop this information by compiling available information, and will consider the need for conducting tests of treatment effectiveness.

7.1 Incineration

Factors Affecting Effectiveness

The same general factors influence the effectiveness of all common types of medical waste incinerators.

- Incineration temperature is one of the factors which influence the effectiveness of an incinerator. High temperatures increase the destruction of organic compounds.
- The residence time of the solid materials in the incinerator is also important. The longer the solids are allowed to remain in the incinerator the more complete the destruction of organic materials will be. However, long residence times for solids reduce the throughput rate of the incinerator. Rotary kilns operate most efficiently when large quantities of waste

are to be incinerated. In contrast, batch incinerators cannot process large quantities of waste efficiently.

- The mixing of the waste with the combustion of high temperature air is another parameter that affects the completeness of the combustion and the treatment effectiveness. Of the three classes of incinerators, rotary kilns are generally the most effective at mixing the solid materials. The kiln's rotation aids in mixing the wastes and helps ensure that no pockets of unburned material are formed. This is particularly useful when carcasses and other wastes with high moisture contents are burned. The large amount of water in these materials tends to cause them to burn more slowly than the surrounding material. If the pockets are not broken up, unburned material may pass through the incinerator.

- The characteristics of the waste can influence incinerator temperature and required residence times. Waste material which contains large quantities of plastics and paper has a high heat content and will burn quickly and produce high temperatures. Wastes which contain large amounts of fluids and large bulky moist objects will burn slowly and produce relatively low temperatures. Additional fuel may be needed to burn large quantities of wet wastes.

Quality Assurance and Quality Control Procedures

Monitoring an incinerator is a relatively difficult task, because the wastes are highly variable. For effective incineration, it is necessary to continuously monitor the incinerator to ensure that the required temperature is maintained, the required quantity of air is being supplied, and the waste's characteristics are appropriately accounted for.

Maintenance and Operator Training

Due to the complexity of incineration systems, relatively frequent maintenance is required. Maintenance includes replacement of worn refractory, removal of ash deposits on walls and ducting, cleaning and replacement of air inlets, and repair of worn mechanical parts.

Because operator training is necessary for effective incinerator operation, EPA has developed a training course for hospital incinerator operators available through the EPA Regional Offices.[1] Course materials have been distributed to State agencies responsible for administering the Clean Air Act that wish to conduct operator training programs. Proper incinerator operating techniques may reduce maintenance and repair cost in addition to reducing air emissions.

7.2 Steam Sterilization

Factors Affecting Effectiveness

Three important factors in steam sterilization processes are temperature, pressure, and exposure time. The size and material of the load, the material of the autoclave bag and the container, and the waste's configuration in the chamber also affect the steam penetration and heat transfer.

For effective treatment, all of the material within a steam sterilizing unit must be exposed to steam at a certain temperature for a sufficient length of time. Materials to be sterilized are generally placed in polyethylene bags which are then placed in a steel or polypropylene container and loaded in the unit. The exposure time can be lengthened to compensate for poor heating or poor steam penetration.

Quality Assurance and Quality Control Procedures

The steam temperature and pressure in the chamber are the parameters routinely monitored. The cycle time can be adjusted by the operator to account for load to load variations in the waste.

Two methods of quality control can be utilized to ensure proper equipment function; chemical indicators and biological indicators. A chemical indicator that changes color when a certain temperature is reached can be used to verify that a specific temperature has been achieved. However, such indicators do not show the length of time the waste has been exposed to steam at that temperature.

Another quality control method involves placing spore strips of Bacillus stearothermophilus in the autoclave with a load of waste. B. stearothermophilus is used as a biological indicator. It is able to survive in elevated temperatures by forming spores. The viability of the destruction of B. stearothermophilus spores during the decontamination period ensures that virtually all heat-resistant bacterial pathogens are inactivated.

Maintenance and Operator Training

Autoclaves require some maintenance. In addition, although they are relatively simple to operate, operator training is needed because of the potential safety hazards.

7.3 Gas Sterilization

Factors Affecting Effectiveness

To be effective, the sterilizing agent in a gas sterilizing unit must be able to penetrate the wastes and must be present in a sufficient concentration. The presence of organic matter or soiling agents on the waste surface can interfere with the sterilizing agent's action. Cycle time, relative humidity, and temperature in the unit also affect the technique's effectiveness.

Quality Assurance and Quality Control Procedures

The effectiveness of a gas sterilization system can be periodically checked using spores of a bacterial species that is resistant to the sterilizing agent.

Maintenance and Operator Training

Some operator training is required to operate a gas sterilization unit because of the potential exposure to compounds such as ethylene oxide or formaldehyde.

7.4 Chemical Disinfection

Factors Affecting Effectiveness

In chemical disinfection, infectious agents must be exposed to a chemical disinfectant that acts against the microorganisms present in the waste. Waste particle size, porosity, and permeability all affect the ability of the chemicals to penetrate the material. Grinding the waste prior to treatment reduces the size of the material, and increases the potential effectiveness of the method. As with gas sterilization, soiling or organic matter present on the waste surfaces can also reduce effectiveness.

Quality Assurance and Quality Control Procedures

Currently, no standard procedures exist to monitor the effectiveness of the treatment. One facility uses a direct contact procedure to culture bacteria present in the waste after treatment.[4] Since the wastes are ground prior to treatment, it is not possible to place a separate container of indicator organisms in the waste to monitor the treatment.

Maintenance and Operator Training

Some periodic maintenance is required; the grinding apparatus in particular is subject to wear. However, little specialized operator training is required.

7.5 Thermal Inactivation

Factors Affecting Effectiveness

The principal factors influencing the effectiveness of heat inactivation are the cycle length and temperature, which are determined by the pathogens' resistance to heat. For dry heat methods, circulation of the heated air is necessary to ensure that all waste reaches the required temperature.

Quality Assurance and Quality Control Procedures

The only continuous monitoring currently available for these units is temperature. Pathogen destruction monitoring involves periodically spiking the waste with a known quantity of heat-resistant bacteria and testing viability after treatment.

7.6 Irradiation

Factors Affecting Effectiveness

To be affected by ultraviolet radiation, microorganisms must have direct exposure to the UV rays for a sufficient length of time. Relative humidity can affect the treatment effectiveness of ultraviolet radiation. With ionizing radiation, higher exposure rates are more effective at destroying infectious agents.[5] However, the minimum required exposure rate has not yet been determined.

Quality Assurance and Quality Control Procedures

As with steam sterilization and gas sterilization, periodic testing with an indicator microorganism may be conducted to ensure that infectious agents are destroyed.

Maintenance and Operator Training

Little routine maintenance is required for irradiation units; periodically the radiation source must be replaced. Extensive operator training is required to operate the equipment.

7.7 Microwave Treatment

Factors Impacting Effectiveness

The volume and density of the waste is an important factor, and affects the required treatment time. Microwaves are limited in their ability to penetrate large and dense objects; thus, this technique is not preferred for treatment of pathological wastes such as body parts or animal carcasses. The microwave frequency is also an important parameter. Increasing the intensity of the microwaves decreases the time required to decontaminate the waste and increases the ability of the waves to penetrate large objects.

Quality Assurance and Quality Control Procedures

Equipment operating parameters such as power and wave attenuation are used to monitor the device on a continuous basis. Direct measurements of pathogen destruction are not made on a continuous basis. As with the majority of the medical waste treatment equipment, pathogen destruction can be tested on a periodic basis through the use of spore strips and spiked samples.

Maintenance and Operator Training

Due to the complexity of the equipment, all maintenance on microwave units must be performed by trained technicians. Operation of the system also requires significant training.

7.8 Grinding and Shredding

Factors Affecting Effectiveness

The principal factors affecting grinding or shredding processes are the quantity of metal and glass present in the wastestream, the size of the waste, and the presence of fibrous, rubber, or soft plastic materials. Metals and glass can wear down the grinding edges, while fibrous, rubber, or soft plastic materials may become caught on the hammermills and cause the equipment to malfunction.

Quality Assurance and Quality Control Procedures

With respect to rendering the waste less recognizable, the operator would observe the shredded waste's size distribution to verify that the equipment is functioning properly.

Maintenance and Operator Training

Grinding equipment requires relatively frequent maintenance due to the wear inherent in the grinding process. Some operator training is necessary if the operators perform the maintenance.

7.9 Compaction

Factors Affecting Effectiveness

Mechanical operation of the equipment is the most significant factor affecting compaction effectiveness. The physical form and composition of the material also have an effect.

Quality Assurance and Quality Control Procedures

Operators can visually inspect the compacted waste to determine if it has been adequately compacted.

Maintenance and Operator Training

Some maintenance is necessary to ensure proper mechanical operation. Operators need little specialized training, unless they perform maintenance.

7.10 References

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CHAPTER 8

EXISTING STATE AND LOCAL REQUIREMENTS

This chapter addresses the requirements of RCRA Section 11008(a)(8), which asks for information on "existing state and local controls on the handling, storage, transportation, treatment, and disposal of medical waste, including the enforcement and regulatory supervision thereof." EPA has responded to this mandate by taking several steps to collect and analyze the regulatory requirements of the ten states targeted for inclusion in the demonstration medical waste tracking program and the two states that have chosen to opt into the program. This chapter describes the requirements of these twelve states (New York, New Jersey, Connecticut, Pennsylvania, Ohio, Indiana, Illinois, Minnesota, Michigan, Wisconsin, Rhode Island, and Puerto Rico) and, to the extent possible, pending proposed regulations.[1] In future reports, EPA will assess the available information on this topic, in relation to the Chapter 9 evaluation of state requirements as appropriate nationwide controls. One focus will be state requirements that appear to be innovative, or appropriate models that are adaptable by other states.

When characterizing medical waste regulations, it is important to be aware of certain characteristics of these rules and the problems they address. Medical waste regulation is both a relatively recent occurrence and a rapidly evolving area of law. Many states are in the process of either developing or amending their regulations in an attempt to address the problems this wastestream poses. The MWTA mandate contributes to this dynamic environment. To understand medical waste regulations it is important to realize that these rules often are the product of more than one administrative agency, and sometimes of different divisions within agencies. Typically, if two state agencies regulate medical waste, the state health agency regulates on-site management and the state environmental agency regulates off-site management.

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[1] The information included here is correct as of June 15, 1989 although some later regulations are summarized.

The term "medical waste" is used frequently throughout this chapter to refer to wastes resulting from health care activities. Various states use slightly different descriptive terms. For example, Minnesota uses the terms "infectious waste" and "pathological waste" to distinguish the differing risks posed by these wastes, and sets different regulatory standards for these two waste types. Similarly, Pennsylvania regulates "infectious and chemotherapeutic waste" but does not use the term "medical waste."

Regulatory Summary

The twelve states can be characterized as states that have medical waste regulations in effect, are presently re-examining, developing or revising these regulations, and have generally chosen comprehensive regulatory programs over more limited ones.

Typical requirements among these states include packaging, labeling, pre-disposal treatment, tracking, and certain permitting requirements. Table 8-1 summarizes the regulatory provisions each state has in place; the remaining sections of this chapter elaborate on what these provisions require and how they are implemented.

Regulatory Status

Of the twelve states discussed in this chapter, ten (Illinois, Minnesota, New Jersey, New York, Indiana, Michigan, Pennsylvania, Wisconsin, Rhode Island, and Puerto Rico) currently have at least some specific medical waste regulations in place. Two of the twelve states (Connecticut and Ohio) do not have medical waste regulations in place. Both of these states are developing regulations which are expected to be in place soon.

Of the ten states with specific medical waste regulations, eight have fairly comprehensive rules, while Puerto Rico and Wisconsin have limited provisions.

Of the twelve MWTA states, only Illinois regulates medical waste as a state hazardous waste. However, Illinois' program does not subject medical waste to typical hazardous waste requirements as much as it sets out specific treatment and transport requirements for medical waste from hospitals. The other states with regulations typically classify medical waste as a special category of solid waste. The regulatory provisions addressing medical wastes range in length from a single paragraph

Table 8-1.
Summary of States' Regulatory Status

	Covered States			Opt Out Covered States						
	NY	NJ	CT	MN	PA	WI[3]	IL[4]	IN	OH[5]	MI
Have Medical Waste Regulations	X	X		X	X	X	X	X		X
Developing/Amending Medical Waste Regulations	X	X	X	X	X	X			X	X
Packaging and Labeling	X	X		X	X	X		X	X	X
Require Treatment[1] Prior to Disposal	X	X		X	X	X	X	X	X	X
Require Records:										
-Generators	X	X		X	X		X		X	
-Transporters	X	X		X	X		X		X	
-Treatment/ Disposal	X	X		X	X	X	X		X	
Require Tracking	X	X			X		X		X	
Require Permits:										
-Generators		X							X	
-Transporters	X	X		X	X	X	X		X	
-Treatment/ Disposal[2]	X	X		X	X	X	X	X	X	X
Exclusions	X	X			X	X	X			

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[1] For at least certain wastes, but not necessarily all wastes.

[2] Permits may be required under other state environmental laws.

[3] Wisconsin's requirements shown here are based on guidelines. Although compliance is not required at present, voluntary compliance is strongly encouraged. Licensed transporters must follow guidelines.

[4] Illinois requirements apply to hospitals only.

[5] Note that Ohio's requirements are based on statute or draft regulations.

Table 8-1.
Summary of States' Regulatory Status (Cont.)

	Opt In Covered States	
	RI	PR
Have Medical Waste Regulations	X	X
Developing/Amending Medical Waste Regulations	X	X
Packaging Requirements	X	
Labeling Requirements	X	
Require Treatment[1] Prior to Disposal	X	X
Require Recordkeeping:		
-Generators	X	
-Transporters	X	
-Treatment/Disposal	X	
Require Tracking	X	
Require Permits:		
-Generators		
-Transporters		
-Treatment/ Disposal[2]	X	X
Exclusions	X	

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[1] For at least certain wastes, but not necessarily all wastes.

[2] Permits may be required under other state environmental laws.

to many pages; the programs vary from a quite limited set of requirements to well developed regulatory programs.

The present status of each state is briefly described below. All twelve states are active in the medical waste area; they are considered to have medical waste regulations if they have specific provisions addressing such wastes. States are not included as having medical waste regulations if medical waste is only subject to the state's nonhazardous solid waste regulations. The twelve states (those states originally specified in the MWTA and those that have opted into the program) are referred to as MWTA states for purposes of this discussion.

- Connecticut is operating under the Federal demonstration tracking program and is preparing to adopt amended medical waste regulations by early 1990. These regulations will be consistent with the Federal regulations, and in some areas may regulate more wastes and/or be more stringent than the Federal regulations.
- Illinois is currently evaluating its medical waste regulations. The Governor has recently appointed a study group to review the existing regulations.
- Indiana has recently finalized medical waste regulations that address the areas of packaging, labeling and treatment.
- Michigan enacted interim medical waste regulations on April 26, 1989, which were intended to address potential problems occurring in the summer of 1989. The rules are similar in scope to the Federal regulations.
- Minnesota has enacted new, comprehensive infectious waste regulations as of May 22, 1989; the waste management and recordkeeping provisions will be effective Jan. 1, 1990. Minnesota's Infectious Waste Control Act contains provisions based on a report produced by the Minnesota Attorney General's office.
- New Jersey responded to 1988's mismanagement incidents by enacting emergency regulations in August 1988 to address the tracking of medical waste. New Jersey passed legislation (March 1989) authorizing the State to adopt

the Federal medical waste regulations, including certain provisions that are more stringent than the Federal requirements. These regulations were adopted in emergency form and became effective on June 26, 1989. New Jersey's legislation requires the study of important issues related to medical waste management such as economics, handling and disposal issues. The regulations described in this chapter are these latest requirements. The state is presently operating subject to the Federal demonstration tracking program.

- New York also initially responded to the mismanagement incidents of 1988 by enacting emergency regulations, and also has plans to implement a long term medical waste management plan. New York also is operating under the Federal demonstration tracking program; for purposes of consistency with the Federal program and enhanced state enforcement capability, New York has recently amended the state regulations to approximate the Federal requirements. These regulations were effective July 10, 1989. The regulations described in this chapter are these latest requirements.

- Ohio has filed comprehensive draft infectious waste rules. The rules are expected to become effective by winter of 1989.

- Pennsylvania has existing regulations that were effective April 9, 1988. The State has enacted legislation (Act 93) which requires the registration of infectious and chemotherapeutic waste transporters, the tracking of such waste, and the review of existing regulations. The State has proposed regulations to implement the requirements of Act 93, and anticipates that they will be effective in the winter of 1990.

- Puerto Rico has limited provisions addressing medical waste, and is considering developing new regulations.

- Rhode Island has regulations that address medical waste management. These regulations were amended in October of 1988, and apply only to health-care facilities and laboratories that are licensed by the Rhode Island Department of Health.

- The State of Wisconsin finalized its medical waste guidelines in May 1989. If medical waste is not properly handled and disposed of, it may violate a number of state laws, including but not limited to, Section 29.29, 144.44, 144.64, and 144.76 of the Guidelines for the Handling and Treatment of Medical/Infectious Wastes. As a result, several penalties may be imposed for violators of those statutes.

Of the twelve states discussed here, those that do not presently have medical waste regulations are Connecticut and Ohio. Connecticut has proposed regulations, which are expected to be finalized in 1990. Ohio has recent legislation that requires the development of medical waste regulations; these regulations have been drafted and should be effective in the next few months. Thus, nearly all twelve states have some form of medical waste regulations, either in place or in the works.

8.1 Definition of Medical Waste

Nine of the ten MWTA States that have existing medical waste regulations include a definition of medical waste in the regulations. Puerto Rico does not presently have a regulatory definition of medical waste. Ohio also includes in its statute a definition of the wastestreams to be regulated. All of these definitions vary, sometimes significantly, in their content as well as in their approach to identifying medical wastes of concern. Some of the definitions only address wastes from specific facilities. For example, only waste from hospitals is regulated in Illinois.

These states use three basic approaches, as well as combinations of these approaches, to define medical waste. First, some states use a definition based on the infectious characteristic of a waste. One state, Wisconsin, defines a waste as infectious if it is capable of causing an infectious disease. The second approach to defining these wastes is listing waste types or categories; for instance, a definition may designate blood and blood products as infectious medical waste. A third approach is to designate such wastes according to their source, such as designating all waste from an isolation patient as infectious medical waste.

All of the states that define medical waste use a definition based on some combination of the approaches described above. A combination of approaches can define the wastes subject to regulation in a manner that limits regulatory coverage to wastes that pose a potential risk. Another reason for the combined approach is that the regulations can be difficult to implement unless the wastes are specifically described, either by designating the source or by using descriptive terms. Wisconsin employs a definition based on the infectious characteristic of the waste in the administrative rule that governs infectious waste; however, Wisconsin's guidelines use categories and the reporting form designates the sources. New York and New Jersey regulate the same seven waste classes regulated under the demonstration tracking program. New York regulates additional wastes as well. Both of these definitions are a combination of the listing and source based approaches.

When the definitions used by states other than New Jersey and New York are compared to the definition contained in RCRA Section 11002, three states include essentially the same types as the non-optional (1-5) medical waste types in the Act. These states are Michigan, Ohio and Pennsylvania. Several other states are close to including the non-optional types. None of the MWTA States, however, match all of the waste types (Sec. 11002 (a)(1-

10)) in the Act. Rhode Island's definition comes close to matching all ten waste types if generators include certain discretionary waste types as medical waste.

Exclusions

Certain states exclude some medical waste from certain management requirements. Wisconsin provides for a small quantity generator (less than fifty pounds per month) exemption from licensing requirements for transportation or storage. Illinois provides for a small quantity generator exemption from tracking requirements. New Jersey exempts generators of less than three cubic feet of medical waste per month from the requirement to use a registered transporter if the generator transports only that waste to another generator for storage or disposal. Illinois and New York also exclude small quantity generators from the requirement to use a permitted transporter. Ohio's statute provides that generators of less than 50 pounds of medical waste per month are not subject to certain generator standards.

New York, Ohio, Pennsylvania, and Michigan also exclude household waste from regulation as infectious waste, and Michigan excludes agricultural businesses. New Jersey excludes waste from self-administered medical care, or care provided by a spouse, family member, or non-profit health care provider. Rhode Island provides for variances where hardship conditions exist and no threat to health would result. Connecticut proposes to exclude household waste. Minnesota's statute currently exempts household, farm operation, and agricultural business infectious or pathological waste from management requirements, but requires the state agencies with jurisdiction to study the issue further.

8.2 Handling

Segregation

Several of the MWTA States expressly require the segregation of medical waste from other wastes. Michigan, Minnesota, New Jersey, New York, Ohio, Rhode Island, Pennsylvania, and Wisconsin require such segregation. Generally, segregation is required at the point of generation, or as soon as practicable after the waste is generated.

Connecticut and Ohio also propose to require (and New Jersey, New York, and Wisconsin require) that sharps be separated from other medical waste. Rhode Island and Pennsylvania require that medical waste posing multiple environmental hazards be segregated for treatment in accordance with regulatory and individual facility management plan requirements.

New Jersey and New York have adopted segregation requirements for fluids in quantities greater than twenty cubic centimeters; this requirement is consistent with the Federal requirement for segregating fluid medical waste. Illinois does not expressly require segregation of medical waste from other waste.

Packaging and Labeling

Most of the MWTA States currently require packaging and labeling of medical waste. Michigan, Minnesota, New York, Pennsylvania, Rhode Island, and New Jersey all have current packaging requirements. Wisconsin recommends such requirements in guidance. Ohio proposes to adopt packaging requirements. Illinois does not have packaging and labeling requirements for medical wastes.

Typical packaging requirements in effect consist of double bagging the waste in polyethylene bags, sealing these bags, and labeling them; sometimes the requirements also specify placing the bags in a second bin, pail, drum, carton or box, which is also sealed and labeled. Reusable outer containers must be kept clean and in good repair.

Several of the states also have special packaging requirements for sharps. Minnesota, New Jersey, New York, Pennsylvania, and Rhode Island provide that sharps must be placed in puncture-resistant containers. Ohio's statute requires that sharps be placed in sharps containers at the point of generation. Usually these containers must also be labeled as infectious waste. In Wisconsin and Minnesota, sharps containers must be handled so as to preclude loss of their contents.

None of the states require that actual medical waste items (e.g., sharps or equipment) be labeled or marked with some form of identification for purposes of tracking; however, New York does require that two floatable identification tags be included in each bag of medical waste.

Storage

Some of the states impose specific storage requirements upon handlers of medical waste. Connecticut, Michigan, Minnesota, New Jersey, New York, Pennsylvania and Rhode Island generally require that medical waste be stored in a sanitary manner, separate from other types of waste, and with limited access. Pennsylvania and Rhode Island also impose limitations on the amount of time medical waste can be stored under various conditions. New York imposes storage time limitations for certain generators (hospitals, nursing homes, and clinical laboratories). Ohio's proposed regulations contain restrictions similar to those mentioned above, including the limitation on the time of storage. Illinois requires permits for off-site storage; the permits require the wastes to be stored in an environmentally sound manner. Indiana's statute specifies that untreated medical waste be stored in a "secure area." Puerto Rico's regulations address control of fires and odors in waste storage areas. Wisconsin has guidelines that address refrigeration and other storage conditions.

8.3 Treatment

Required medical waste treatment typically consists of incineration or some form of decontamination (steam, chemical or other). Illinois, Pennsylvania, and Rhode Island specify in their regulations that medical waste must either be incinerated or sterilized prior to sanitary landfill disposal. New Jersey and New York specify that medical waste must be incinerated, sterilized, or otherwise decontaminated, while Wisconsin specifies incineration or other treatment to render the waste non-infectious. Puerto Rico requires incineration or sterilization prior to burial in a landfill.

In most of the states, treatment must meet some specified standards. Frequently, these are general performance standards that require treatment to render the waste non-infectious; occasionally, design standards are included. For incineration, several states refer to other regulatory provisions which specify standards for incinerator performance and/or design.

Of those states with developing regulations, Connecticut proposes to require incineration or sterilization, and Indiana's statute requires effective treatment (reduction of pathogenic qualities to safe levels). Ohio's draft regulations require treatment which renders the waste non-infectious; allowed methods are incineration, autoclaving, and chemical treatment of cultures.

The various states do not all require that the same wastes be subject to treatment, or that similar wastes be subject to the same treatment. Three factors contribute to these differing treatment requirements. First, as noted previously, each of the states defines medical waste in a different manner. Second, the states do not all regulate the same generators of medical waste. Certain states require treatment for only one group of generators; in Illinois only hospitals have waste treatment requirements. Others, such as Pennsylvania, require treatment for any waste which meets the characteristic or waste type criteria in that state's definition. Finally, some states, such as Rhode Island, specify different treatment methods for different categories of medical waste. For instance, liquid wastes from microbiological laboratories must be autoclaved, while pathological wastes must be incinerated.

Pennsylvania requires that sharps be rendered unusable prior to disposal, while Rhode Island requires that they be treated. New Jersey provides under a separate criminal justice statute, directed toward control of intravenous drug abuse, that needles and syringes discarded or abandoned in any public or private place, accessible to any other person, must be destroyed. For needles this means breaking the needle from the hub or mangling the needle, and for syringes this means breaking the nipple from the barrel, or melting the plunger and the barrel together. Destruction of the entire hypodermic (needle and syringe) is also acceptable if accomplished by grinding, crushing or incinerating the entire unit, or by any other method approved by the department of health. Minnesota prohibits sharps from being compacted, or from being disposed at facilities where waste is hand-sorted.

8.4 Disposal

Medical waste is typically disposed either through landfilling or sewer disposal. Most states require treatment of these wastes prior to disposal. All ten of the twelve states discussed here that have current medical waste regulations require the treatment of some medical wastes prior to landfill disposal. Minnesota does allow untreated medical waste to be landfilled if the disposal facility has been issued a special permit. Ohio's statute requires such treatment prior to land disposal. Rhode Island has recent legislation prohibiting landfilling of medical waste at state facilities.

With respect to treatment residues, some of the states have specific provisions for the disposal of ash; most of the states consider treated medical waste (either ash or treatment residue) as solid waste, to be disposed of in a manner consistent with their solid waste regulations (i.e., landfilled). For example, ash in Illinois is considered a special waste and disposal requires special permitting.

One method of disposal where treatment requirements differ significantly from those for landfilling is sewer disposal. Nine states do not require the treatment of liquid medical waste before it is sewer disposed. Most of these states place minimal restrictions on such disposal and require that it be consistent with existing state sewer regulations. New York, Illinois, and Indiana allow the disposal of untreated liquid or semi-liquid medical waste to the sewer system under applicable regulations. Pennsylvania allows disposal of blood, urine, feces and other body fluids if the system has secondary treatment. Ohio allows blood, body fluids, and excretion to be discharged to a disposal system provided the discharge is consistent with the system's water pollution permit. New Jersey allows untreated bulk blood to be sewer disposed, but requires liquid microbiological laboratory wastes to be autoclaved before sewer disposal. Rhode

Island allows sanitary sewer disposal of bulk blood and body fluids where permission is granted from the sewer authority and other conditions are met. Wisconsin, Minnesota, and Puerto Rico do not expressly address sewer disposal in their medical waste regulations. Wisconsin requires treatment before disposal in a solid waste disposal facility, and thus apparently allows sewer disposal, while Minnesota generally allows sewer disposal, treating it as a matter for local regulation.

8.5 Recordkeeping and Reporting

States have begun to impose recordkeeping requirements on medical waste generators, transporters, and treatment/disposal facilities in an effort to collect information on this wastestream and thus better control it. For example, New Jersey requires generators of 300 or more pounds per year to complete daily logs of medical waste generated, treated, or disposed on-site, and/or sent off-site. (Generators of less than 300 pounds per year must maintain similar logs on a monthly basis.) New York and Illinois require generators to maintain records of on-site treatment and destruction. Minnesota requires generators and other waste handlers to prepare management plans; these plans include descriptions of waste handling procedures, and a statement of the waste quantities handled.

Connecticut proposes to require transporters to maintain logs which indicate for each shipment the quantity and shipment dates of medical waste transported, and the source and delivery points for the waste. Ohio's draft regulations require generators to keep monthly totals of generated waste quantities. In addition, states that require the tracking of medical waste generally require generators, transporters, and disposal facilities to maintain records of tracking form information.

With respect to treatment/disposal facilities, Illinois currently requires medical waste treatment facilities to keep records of the amounts treated, treatment effectiveness, and operation of treatment equipment. Pennsylvania requires the submission of certain treatment analyses. New York requires facilities to maintain records of the waste handled. Connecticut proposes to require steam sterilization units to maintain logs containing information on the operation and effectiveness of each treatment operation. Ohio's draft regulations require treatment facilities to keep records of waste quantities received, and operational/maintenance/quality control logs.

In addition to recordkeeping, certain information must be submitted to the states in the form of reports. New Jersey requires that an annual medical waste generator report be submitted; facilities that treat, destroy, or dispose medical waste also must submit annual reports. New York requires medical waste generators and transporters to submit annual reports. Consistent with the Federal requirements, New Jersey and New York require generators who incinerate medical waste on-site to submit periodic reports. Minnesota requires that waste management plans be submitted periodically.

Connecticut proposes to require generators to prepare annual reports summarizing the information from all tracking documents generated during the year, including a description of the waste generated and transported off-site, the quantity by weight of such waste, transporter information, and treatment and disposal facility information. Ohio's draft regulations require generators and treatment facilities to submit annual summaries including information on infectious waste quantities generated or received.

As part of the development process for medical waste regulations, Pennsylvania is conducting a study of medical waste generation and management. Wisconsin is requesting reporting from treatment facilities (primarily incinerators), and from landfill operators. Information requested includes source, amount and type of waste, treatment method, and final disposition.

8.6 Tracking

Several of the MWTA states either currently require or propose to require the tracking of medical waste. In every case where tracking is required or proposed, the tracking system consists of manifesting the waste from the point of generation through disposal. Pennsylvania, Illinois, New Jersey, New York and Rhode Island currently require such tracking, while Connecticut proposes to adopt such requirements. Ohio's draft regulations require shipping papers to accompany shipments of treated infectious waste.

Pennsylvania has required a four-part manifest for generators and an eight-part manifest for hospitals since March

1, 1990. Ohio's draft regulations require a multi-part form, with each handler retaining a copy. After the infectious waste is treated, a copy of the shipping paper is returned to the generator as assurance that the waste has been properly treated. Another shipping paper accompanies the shipments to a licensed disposal facility. Pennsylvania's regulations require hospitals to complete an eight-part manifest; proposed regulations would require all other generators to complete a four-part manifest.

New Jersey and New York utilize four part tracking forms. These States require that copies of the completed tracking form must be sent back to the generator within 35 days of shipment; if a copy is not received by the generator within 45 days of shipment he or she must notify the regulatory authority. Connecticut proposes to require tracking under provisions similar to the Federal tracking requirements.

Illinois utilizes a six part tracking form, and requires generators to submit a copy of the tracking form to the state when it is first completed by the generator. The treatment/disposal facility must send copies of the manifest to both the generator and the State of Illinois on a monthly basis.

8.7 Permitting/Licensing

Permitting and/or licensing can give the regulating authority additional control over the parties involved in waste management. This section summarizes specific medical waste management permitting requirements. A somewhat lesser, but related form of control is registration. This chapter does not attempt to distinguish between these forms of control, but future reports will examine these mechanisms.

Ohio proposes to require all generators of over 50 pounds of medical waste per month to register with the state. New Jersey also has registration requirements for all generators of regulated medical waste. The other states focus on requiring the registration of transporters.

Pennsylvania, Illinois, Minnesota, New Jersey, and New York require medical waste transporters to have permits or register with the state. Connecticut and Ohio propose to require registration for transporters. Wisconsin requires that medical waste be transported by a licensed service.

Some of the states provide for exemptions from transporter permitting requirements. Pennsylvania allows generators of less than 100 kg/month to transport their own waste without a permit. Illinois provides that generators of less than 100 kg of medical waste per month are exempt from transporter permitting requirements. For generators of under 50 pounds of medical waste per month, Ohio provides exemptions from having to utilize registered transporters; New York allows these small generators to transport their own waste without a permit if they have notified the State of New York.

Medical waste treatment facilities include incinerators and sterilization facilities. Ohio's draft regulations address permitting treatment facilities with specific requirements, and require licenses in addition to permits issued under the Ohio Division of Air Pollution Control. Most of the MWTA states currently require permits for incinerators under air quality regulations; the permits may or may not specifically address issues related to medical waste treatment.

Landfills also generally require permits; however, like incinerator permits, landfill permits generally do not focus on medical waste management issues. Exceptions are in Ohio and New Jersey, where disposal facilities must have permits and licenses to accept medical wastes. In Pennsylvania, landfills must obtain specific permit approval for processed infectious and chemotherapeutic waste.

8.8 Enforcement

EPA has limited information at present on states' enforcement of their state medical waste regulations, but is developing an information clearinghouse that will contain this information. In future reports, this information obtained will be described. At present, EPA is only aware of the substantial penalties available in Minnesota, ranging from administrative to civil and criminal penalties. Administrative penalties may be up to $10,000; civil penalties may be imposed up to $10,000 per day of violation. Criminal penalties of up to $10,000 and/or one year imprisonment ($25,000 and/or up to two years imprisonment for subsequent offenses) are available.

8.9 Summary

In summary, there are a variety of existing controls on medical waste management that are imposed by the twelve MWTA states (Connecticut, Illinois, Indiana, Michigan, Minnesota, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Wisconsin, and Puerto Rico). The controls range from none at present (Connecticut and Ohio) to regulating hospital waste as a type of hazardous waste (Illinois). Many of these states have chosen to impose packaging, storage, treatment, and tracking requirements, and some impose disposal limitations as well.

CHAPTER 9

REGULATORY OPTIONS FOR A NATIONAL PROGRAM

Section 11008(a)(9) of RCRA requests an evaluation of the "appropriateness of using any existing State requirements or the requirements contained in Subtitle C as nationwide requirements to monitor and control medical waste." In conducting this evaluation, EPA will carefully review existing State medical and infectious waste requirements, and will also consider elements of the Subtitle C program to assess the need for a national medical waste monitoring and control program.

In Section 11008(a)(9), EPA interprets the word "monitor" to mean the tracking or awareness of a waste's movement, in order to assure that it is ultimately disposed of properly. Packaging, labeling, and marking requirements are part of a monitoring program, as are recordkeeping and reporting requirements associated with the waste's movement. Several alternatives available to track or monitor medical waste have been presented in Chapter 4. In future reports, this chapter will discuss the appropriateness of nationwide tracking requirements generally, as well as the appropriateness of storage, treatment, and disposal standards to "control" medical waste on a nationwide basis. Several program implementation issues will be evaluated (e. g., the need for facility permits, additional reporting requirements, and generator/disposer identification numbers). Innovative relationships between EPA and the states, to improve program implementation, will be evaluated as well.

9.1 Nationwide Tracking

The first issue in evaluating the need for nationwide tracking requirements is the impact of mismanagement on public health and the environment. To the extent possible in the final report, EPA expects to weigh the results of the health and environmental impact study outlined in Chapter 2, the costs of mismanagement developed in Chapter 3, and the "success" of the demonstration program evaluated in Chapter 4, in order to present a recommendation on the need for a nationwide tracking program that is similar to the present demonstration program.

The need for a Federal presence in intrastate medical waste shipments is one activity to be considered in examining regulatory options. Federal regulation of interstate shipments to promote uniformity will also be examined. Experience with the hazardous waste program has shown the need for uniform information requirements which accompany hazardous waste shipments.

EPA will consider comments received on the March 24, 1989 interim final regulation in determining whether the program should be expanded nationwide (with any changes deemed appropriate after analysis of the public comments), and will consider whether certain elements of the Subtitle C program (e.g., identification numbers for generators and treatment or disposal facilities) should be incorporated into a national tracking program.

9.2 Development of Control Options

EPA intends to review state regulations and the Subtitle C requirements, and to evaluate these and other requirements as appropriate medical waste control and monitoring methods. The options prepared will then be evaluated to address costs, advantages and disadvantages, and implementation and effectiveness. Most importantly, EPA will consider information on the health hazards of medical waste to determine the extent of control needed for the various management practices.

Controls will be evaluated for the following waste management practices:

Storage. EPA intends to evaluate the need for storage requirements, at the generator's site or prior to off-site treatment or disposal. Individual state requirements, the storage requirements for hazardous waste, and other options will be addressed in the context of the potential public health hazards from current storage practices.

Treatment. Chapters 6 and 7 present an evaluation of the available treatment technologies. The different techniques' effectiveness may vary substantially from process to process and from cycle to cycle; in future reports, EPA will evaluate their effectiveness and will attempt to incorporate this information into the health hazard assessment described in Chapter 2. A review of existing state regulations may find appropriate requirements for the various treatment options. Under the Subtitle C regulations, treatment of hazardous waste generally requires a permit. As previously discussed, EPA has begun developing regulations for hospital incinerators under the Clean Air Act.

Disposal. After evaluating health impacts, EPA will consider whether any state requirements are appropriate, or whether some form of treatment standards should be placed on certain types of medical wastes that are disposed in landfills.

EPA will also consider whether any controls needed should be implemented through a facility permitting program, or through other means of compliance determination.

9.3 Federal/State Relations

A number of implementation issues arise when considering a nationwide program for monitoring and controlling medical waste. EPA will consider the Subtitle C approach, with its structured state authorization process, and a range of other, less structured approaches which could include:

- A model state program approach, in which states may choose elements of a program which reflect state or regional priorities. States could select the most appropriate elements, and enforce and implement the program using their own state authorities.

- An approach where states adopt minimum federal regulations verbatim, using state authority, and include additional requirements which they determine are necessary. This approach raises several enforcement and implementation issues which EPA will explore.

- The approach adopted under the RCRA Subtitle I program, which requires a state seeking to implement a program to demonstrate that the state's requirements and approach for each of several program elements are no less stringent than the federal program.

In future reports, EPA will evaluate the advantages and disadvantages of the various approaches, and will continue to identify other approaches.

9.4 Export of Medical Waste

Due to increasing international concern about exports of various wastestreams, EPA and other Federal agencies are evaluating waste export practices in general. Current RCRA authority for regulating exports is limited to exports of hazardous waste. At this time EPA does not plan to list medical wastes as hazardous wastes; thus, transboundary movement of medical waste is not subject to the hazardous waste export notification requirements. However, the recent United Nations Environmental Program (UNEP) global convention on hazardous waste exports would place restrictions on transboundary movement of a broad range of waste, including infectious waste. The United States is studying the convention.

In evaluating the need for restricting medical waste exports, EPA will consider the export restrictions developed under Subtitle C for hazardous waste. These restrictions, found at 40 CFR 262.50 to 262.58, impose requirements on certain generators to provide an advance notification of their intent to export hazardous waste. If EPA obtains an Acknowledgement of Consent from the receiving country, the shipment can take place, provided certain additional requirements are met by the exporter. EPA will evaluate these requirements as possible controls on the transboundary movement of medical waste. EPA will also consider other, more stringent controls that would be required if the U.S. choses to ratify the UNEP convention.

In addition, EPA will reconsider the appropriateness of the Subtitle J requirements for regulated medical waste exports. The regulations at 40 CFR 259.53 require the generator to request the receiving facility to provide written confirmation of the waste's receipt. In Section 259.74(e), transporters who transport regulated medical waste across an international boundary or deliver the waste to certain receiving facilities in a foreign country must sign the tracking form and verify delivery. The transporter then provides written confirmation to the generator by mailing the signed copies of the tracking form. EPA took this approach because of the lack of authority to require foreign facilities to sign and return tracking forms.

EPA intends to evaluate the comments received on the March 24, 1989 interim final rule, and will continue to identify other possible approaches to controlling transboundary movement of medical waste.

CHAPTER 10

APPROPRIATENESS OF PENALTIES

Section 11005 of Subtitle J provides civil penalties of up to $25,000 per day of noncompliance. Administrative orders assessing civil penalties must take into account the seriousness of the violation and any good faith efforts to comply with applicable requirements. In addition, civil penalties assessed by the United States or the States must be in accordance with EPA's "RCRA Civil Penalty Policy." That policy sets out EPA's policy for determining appropriate administrative penalties for violations under Subtitle C.

Calculating penalties under the policy consists of: (1) determining a gravity-based penalty for a particular violation; (2) considering economic benefits of noncompliance, where appropriate; and (3) adjusting the penalty for special circumstances, such as respondents' good faith efforts to comply, their degree of willfulness or negligence, compliance history and ability to pay. On March 30, 1989, EPA issued guidance[1] on use of the policy for determining civil penalties, in both administrative and civil cases, for Subtitle J violations.

In addition to civil penalties, Subtitle J provides for imprisonment of up to two years or a fine of up to $50,000 per day of violation for criminal violations. Criminal violations involving knowing endangerment are punishable by imprisonment of up to 15 years or a fine of up to $250,000, $1,000,000 for defendants that are organizations.

Section 11008(a)(10) of Subtitle J requires EPA to report to Congress on:

> The appropriateness of the penalties provided in Section 1100[5] for insuring compliance with the requirements of [Subtitle J], including a review of the level of penalties imposed under this subtitle.

(Note: this provision erroneously refers to Section 11006. As is clear from the legislative history, the reference was intended to be Section 11005.)

EPA views that the report required by Section 11008(a)(10) must address two questions: first, whether penalty maximums provided by Section 11005 are appropriate for Subtitle J violations, and second, whether civil penalties assessed and collected for these violations are appropriate with respect to their being in accordance with the RCRA Civil Penalty Policy. These two questions are related since use of the penalty policy allows for assessing civil penalties below statutory maximums.

There is no data at this time upon which to base any conclusions. Final penalty determinations are made only after discovery of violations and the conclusion of the settlement or litigation process. The demonstration program is still too new for this to have occurred.

EPA's efforts at this time, therefore, concentrate on collecting information that will form the basis for analyses in the second interim and the final Report to Congress. EPA is currently setting up procedures for collection by EPA headquarters of administrative and judicial complaints, orders and decrees issued under Subtitle J.

These information collection procedures will cover EPA Regions, participating states, and the U.S. Department of Justice.

EPA is also considering a review of penalties obtained by States using their own legal authorities for violations involving medical waste management practices. EPA recognizes that it may be difficult to identify and collect information on these State violations and then compare it to information involving specifically federal violations. These comparisons, however, may shed some light on what is an appropriate penalty level, especially since there likely is no direct data on what penalty levels ensure compliance. In addition, the amount of information on penalties for federal violations may be limited due to concerns regarding the constitutionality of States' use of direct federal authority.

At this point, EPA does not plan any analyses of civil penalties for violations of State authorities that would require determinations of what penalties would have resulted from the use of the RCRA Civil Penalty Policy. EPA believes there is little value in making these after-the-fact determinations in an area where decisions are very case specific and necessarily involve the exercise of some subjective judgment and enforcement discretion.

10.1 References

1. U.S. Environmental Protection Agency. *Guidance on Use of RCRA Civil Penalty Policy in Assessment of Penalties Under the Medical Waste Tracking Act of 1988*, Washington, D.C., March 30, 1989.

CHAPTER 11

HOME HEALTH CARE AND SMALL QUANTITY GENERATOR WASTE

This chapter addresses the information requested in RCRA Section 11008(a)(11) relating to waste generated from home medical care. Because EPA encourages health care professionals to transport these wastes from the patient's home and manage them as regulated medical waste, the guidelines provided in this chapter are intended for wastes from individuals who self-administer medical care in their homes.

Section 11008(a)(11) also requests information on the effect of excluding small quantity generators from medical waste management regulations, and potential guidelines for small quantity generator handling of medical waste. Discussions with state officials and health care organizations indicate that under the definition of "regulated medical waste" in the EPA rule, the universe of generators in the less than 50 pounds per month category would be extremely large (in excess of 100,000). As a result, EPA has determined that some form of exemption from the full tracking requirements is appropriate for generators of less than 50 pounds per month, because the paperwork burden resulting from tracking each shipment individually would overwhelm generators, transporters, treaters and disposers. Requiring tracking forms to accompany shipments from all generators, regardless of size, could make the whole tracking system virtually impossible to administer and thus ineffective.

Therefore, generators of less than 50 pounds per month of regulated medical waste are responsible for: proper packaging, labeling, and marking of waste; use of transporters who have notified EPA; and use of a log to record when waste is transported off-site (see §259.50(e)(2)). These generators are not required to complete a tracking form for each shipment, nor are they required to comply with the associated exception reporting requirements. These two exemptions should result in a significant reduction of the paperwork burden for medical waste managers. EPA believes this limited exemption achieves the appropriate balance between the need to ensure that even very small quantities of medical waste are properly managed and the need to develop a program that can be quickly and easily implemented. To the extent that management practices of small quantity generator medical waste affect the demonstration program, the effects will be discussed in future reports.

As a result, EPA has determined that some form of exemption from the full tracking requirements is appropriate for small quantity generators (generators of less than 50 pounds per calendar month), because the program's success would be affected by the burden of unnecessary paperwork. However, waste from these generators is not completely excluded. Therefore, this Chapter deals primarily with household-generated waste.

11.1 Background

Skyrocketing health care costs have resulted in shortened hospital stays, increased availability of out-patient treatment and diagnostic procedures, and a general trend toward home health care for post-surgical, terminally ill, and bedridden patients. As a result, each year millions of patients undergo treatment and diagnostic procedures at home. A significant portion of this care is provided by family members and friends; however, home health care providers such as visiting nurses and medical technicians also provide health care. In many cases home health care is self-administered (e.g., diabetics often self-administer insulin).

If this trend in home health care continues, the number of medically related devices used at home and disposed of in household waste will also increase. Once disposed of in the domestic waste stream, these wastes may pose a potential risk of injury to family members and refuse workers. The potential risk of infection from these wastes generally appears to be minimal. In Chapter 2 a procedure for evaluating the infectious and injury hazards of medical wastes was outlined. Waste items generated from home health care, although excluded from the definition of medical waste, differ from some of the Section 11002 waste types only in their source (e.g., sharps). EPA anticipates that the type of health hazards from home health care wastes will be similar to those from medical wastes; however, the degree of hazard may differ. In a future report we will address the degree of potential hazard.

Section 1004(40) of RCRA specifically excludes any household waste, as defined in regulations under Subtitle C, from the definition of "medical waste." [Household waste is defined in 40 CFR 261.4(b)(1) as material derived from households, including single and multiple residences, hotels and motels, bunkhouses, ranger stations, crew quarters, campgrounds, picnic grounds, and day-use recreation areas.] Thus, waste generated from home health care is excluded from tracking, segregation, and packaging requirements under Subtitle J of RCRA and, therefore, remains unregulated unless covered by State or local regulations. However, section 11008(a)(11)(A) of the Medical Waste Tracking Act requires EPA to report on the effect of excluding households (and small quantity generators) from regulation. Section 11008(a)(11)(B) requires the Agency to establish guidelines for the handling, storage, treatment, and disposal of these wastes.

In carrying out the congressional mandate under section 11008(a)(11)(A), the Agency plans to refine its estimate of the quantity of health care waste which is being generated in households. In conducting this evaluation, EPA is comparing the home health care wastes to the medical waste types listed in section 11002 of the Medical Waste Tracking Act or regulated at 40 CFR 259.30(a) and will evaluate potential impacts on public health and the environment from excluding such waste from Subtitle J regulation. In response to section 11008(a)(11)(B), this report also describes the educational activities currently underway.

This section of the report to Congress provides available estimates on quantities of household healthcare waste generated per year and outlines EPA's strategy for public education on proper management and disposal of these wastes. The following specific topics are addressed:

- identification and characterization of home health care waste,
- estimated quantities of health care waste generated and disposed of from households,
- impacts from excluding home health care waste from regulation under Subtitle J,
- EPA's home health care waste education program,
- recommendations for safe handling of home health care waste, and
- alternative disposal options.

11.2 Identification and Characterization of Home Health Care Waste

The first step in identifying the waste items generated from home health care that are listed in section 11002 or regulated under Subtitle J requires certain information regarding typical home health care practices (i.e., the types of treatment and diagnostic procedures generally conducted in the patient's home). The following medical procedures are often administered to elderly and acutely and chronically ill home care patients:[1]

1. dialysis
2. administration of medication by injection, nebulization (i.e., fine mist or spray), or IV (i.e., parenterally)
3. respiratory care
4. total parenteral nutrition (i.e., feeding by IV)
5. suctioning of body fluids

6. changing of surgical dressings
7. sanitizing of equipment and other medical devices

Although this list is not exhaustive, it includes procedures that are likely to generate wastes that may pose health hazards to family members or waste handlers. These wastes may be infectious, aesthetically displeasing, or result in physical injury.

Wastes generated from these procedures often vary in quantity and type due to variations in treatment regimen, frequency and duration of treatment or diagnostic procedure, and general condition of the patient. For example, care of acutely ill patients may generate needles and syringes (i.e., sharps) from administration of medication, IV sets, suction tubing, dressings and gauze containing blood and body fluids, and other wastes depending upon treatment regimen or diagnostic procedure.[2] Diabetics typically generate needles and syringes from self-administration of insulin and, to a lesser extent, lancets from blood glucose tests. Wastes from home dialysis vary according to dialysis method. Needles, filters (dialyzers), and tubing are generated from hemodialysis; however, peritoneal dialysis typically generates dialysis bags.[3] Although many home care patients require respiratory support, the equipment is generally sanitized for reuse and spent disinfecting solutions are discharged to the sewer or septic system.[4]

The following materials and medical devices are some of the waste items listed in RCRA section 11002, or in the RCRA Subtitle

J regulations at 40 CFR Part 259, and are likely to enter the domestic waste stream from administration of the home health care procedures identified above:

1. used and unused sharps such as needles and syringes, and lancets
2. IV sets including tubing and bags
3. dialysis sets including tubing, filters and materials contaminated with the blood of patients undergoing dialysis
4. soiled surgical dressings and other materials contaminated with blood or blood products (e.g., gloves, gauze, dressings, disposal pads, etc.)

EPA does not expect the waste types listed in RCRA section 11008 (a)(1), (a)(2), (a)(5)-(a)(7), (a)(9), or (a)(10) to be generated in home health care settings in significant quantities. Finally, items such as syringes and needles that have been used by intravenous drug abusers may be considered as household waste. The next report should provide some data on quantities of household waste generated by drug abusers.

11.3 Estimated Quantities of Home Health Care Waste

The data presented here are derived from published information from national organizations, and discussions with medical device manufacturers and home health care representatives. The estimates presented represent minimum volumes of home generated health care waste because limited data exist with respect to total numbers of patients receiving such care. Although some data are available from studies on total volumes of medical waste generated from health care institutions such as hospitals and clinics, minimal data are available on the prevalence of waste generated from home health care. EPA will continue to explore the availability of data, and will report findings in the subsequent interim report. The final report will address data gaps and research needs.

Estimated Number Of Sharps

Diabetics. Approximately 1.4 billion insulin syringes were used by outpatients in 1987.[5] However, this estimate may include syringes generated from hospital outpatient clinics, as well as those generated in other places where diabetics self-administer medication. An estimate of one billion insulin syringes used in home care in 1987 is derived from another source,[6] which yields an estimate of over 1 billion syringes used by diabetic outpatients.

Approximately 300 million self-administered blood glucose tests were performed by diabetics in 1987.[7] These tests require a lancet for blood letting. Thus, assuming a single use of each lancet, 300 million can be used as an estimate for lancets generated and disposed of per year.

Dialysis. There were approximately 5,000 home hemodialysis patients during 1986. Each of these patients used, on average, 18 needles per week.[8] Thus, approximately 5 million needles and syringes per year are generated from home hemodialysis patients.

Total Parenteral Nutrition (TPN). There are approximately 4,000-6,000 patients receiving TPN (i.e., intravenous (IV) feeding) at any given time during the calendar year. Each patient uses, on average, 4 sharps per day for administration of fluids and ancillary drugs.[9, 10] Therefore, the estimated number of sharps per year from TPN is 6-9 million.

Total Sharps Generated From Home Health Care Per Year. In estimating total sharps generated and disposed of per year, the Agency used the upper bounds of the estimated ranges. Thus, the data estimates that approximately 1.4 billion sharps per year are used and discarded in domestic waste streams. This estimate is based on the assumption that all sharps used in home health care are disposed of in household trash receptacles (i.e., sharps are not transported outside of the home for disposal at hospitals, clinics, or other facilities). It may overestimate the total number in household trash, because diabetics may self-administer medication at locations other than the home (e.g., in the workplace or places of recreation) and some may be removed from the home by health care providers. It is important to recognize that these figures do not include patients who may be receiving intravenous antibiotics or chemotherapeutic drugs. Also, figures are not currently available for patients who self-administer allergy injections. However, the Agency has been informed by the National Institutes of Health that allergy patients are advised against self-administering allergy injections.

Estimated Quantities of Home Health Care Wastes Other Than Sharps

Dialysis Wastes. Approximately 80,000 waste dialyzing units from home hemodialysis patients were generated in 1986.

Approximately 10,500 renal patients received continuous ambulatory peritoneal dialysis, which generated 15.3 million waste fluid bags per year. It is estimated that at least one half of these patients also disposed of tubing sets at each change of fluid. Therefore, a minimum of 7.6 million tubing sets must also be considered as waste generated by patients being treated at home (assuming the fluid changes are made in the patients' residences). Actual volumes generated are expected to be higher because an accurate assessment requires data on the actual frequency of tubing changes.[11, 12]

Total Parenteral Nutrition. Approximately 1.5 million fluid bags per year are generated and disposed of from home health care patients receiving IV feedings.[13]

Total Estimates For Wastes Other Than Sharps. Since there are no reliable estimates on the numbers of patients being treated at home for the wide variety of medical conditions that may result in other waste items, EPA cannot at this time provide an estimate. It is likely that these wastes are only a small proportion of the total residential waste stream. We will address the feasibility of conducting a study to obtain needed information.

11.4 Effects of Excluding Home Health Care Waste From Regulation under Subtitle J

An evaluation of the impacts from excluding household medical waste from regulation requires information on the universe of patients receiving medical care at home, estimates of waste generation rates per patient, current household medical waste disposal practices, and an assessment of the effects of the exclusion on municipal waste handlers and potential public exposure.

Although the home health care waste stream has not been completely characterized here, the results in Table 11-1 show that, except for sharps, the wastes identified are generated in very small quantities when compared to the regulated medical waste estimates in Chapter 1. The Agency has determined that significant numbers of sharps are generated in the home health care setting, and that sharps pose hazards of physical injury and have the potential to transmit pathogens and cause infection. Therefore, EPA has initiated an education program aimed primarily at sharps used in home health care.

11.5 EPA Home Health Care Waste Education Program

The Agency has implemented the initial phase of its household health care waste educational program. The primary focus of the program is to provide guidance on proper packaging and disposal of home health care waste prior to placement in the household waste stream. Through public education, the Agency hopes to reduce potential risks to family members and refuse workers from improper management of wastes such as sharps.

The Agency has developed guidelines for proper management of medical waste from home health care (see Section 11.6 below). In addition, the Agency is co-sponsoring a public service message which summarizes guidelines for safe packaging of sharps and other household medical waste (see Exhibit 11-1). The message

TABLE 11-1
Estimated Annual Quantities of Home Health Care Waste, by Source and Waste Type

Waste Type	Sources and Quantities (millions)		
	Dialysis	Diabetics	TPN
Needles & Syringes	5.0	1,400	9.0
Lancets	N/A	300	N/A
Tubing	7.6	N/A	**
IV and Fluid Bags	15.3	N/A	1.5
Equipment Filters	.08	N/A	N/A

** = Information Not Available

Waste Type	No. of items (millions)	Weight (tons)
Needles & Syringes	1,400	7,000
Lancets	300	150
Tubing	7.6	950
IV and Fluid Bags	16.8	1,000
Equipment Filters	.08	40

SOURCE: References 5-13

highlights sharps disposal; however, it also includes guidance on disposal of other home health care wastes such as soiled dressings, gloves, etc. EPA, in conjunction with the other sponsoring organizations, has also prepared an information brochure for health care professionals, which provides background information on the EPA medical waste program. It was designed for use by those disseminating the public service message to patients or persons who use or purchase sharps for home health care (see Exhibit 11-2).

These guidelines represent minimum recommendations for citizens to package their wastes from home medical care. Some States and localities may recommend additional procedures. Options for developing a long-term approach to managing these wastes are presented in Section 11.7.

11.6 Recommendations for Packaging, Storage, and Disposal of Home Health Care Waste

This section provides detailed guidelines for proper packaging, storage and disposal of wastes from home health care. Although such waste is not "medical waste" as the term is defined in RCRA Section 1004(40), EPA recommends that health care professionals providing home health care remove these wastes from the patient's home and manage them as regulated medical waste.

Designated Household Health Care Waste

EPA recommends that the following wastes from home health care be placed in protective packaging before placement into household trash receptacles:

- needles and syringes, lancets, and other sharps
- materials soiled with blood or blood products (e.g., gauze, dressings, disposable sheets and pads, tubing and catheters)
- other medical devices (e.g. peritoneal dialysis bags)

Recommended Packaging and Handling Methods

Needles and Syringes, Lancets, and Other Sharps. These materials should be placed in a tightly closed, hard plastic or metal container before disposal in household trash receptacles. The Agency does not recommend the use of glass containers or soft plastic containers. Glass containers may break, and soft plastic containers may tear or puncture during handling. Examples of hard plastic and metal containers typically present in the household are:

- metal coffee cans
- hard plastic milk or juice containers
- hard plastic soft drink or beverage containers

To avoid spillage, the Agency recommends that caps be tightly fastened. Non-screw caps and lids (e.g., plastic coffee can lids) should be secured with heavy duty tape such as duct tape. While the containers are being used to accumulate the sharps, EPA recommends storing them out of the reach of young children.

In its 1986 guidance document, the Agency states that "clipping of needles is not recommended, unless the clipping device effectively contains needle parts which might otherwise become airborne and pose a hazard" and "devices used to clip needles within a totally enclosed system are acceptable."[14] These devices are available commercially and may be used in home health care. However, when such devices are not available, the Agency continues to discourage clipping of needles. Recapping of needles should likewise be avoided due to risk of needlestick injury. Where State or local law requires destruction of needles before disposal, patients and health care workers should consult with State or local officials for further information.

Gauze, Dressings, Disposable Sheets and Pads Soiled With Blood or Blood Products. These materials should be placed in tightly secured plastic bags before disposal in household trash receptacles. Although plastic bags are preferred because they resist fluid leakage, when plastic is not available heavy-duty paper bags (e.g., supermarket paper bags) may be used. Items to be placed in paper bags should be wrapped in absorbent paper (such as newspaper or paper towels) before placement in the bag. This practice will help to absorb fluids and reduce seepage. Paper bags should also be tightly secured with rubber bands, string, tape, or plastic fasteners.

In cases where materials are saturated or dripping with blood or body fluids, the Agency recommends wrapping these items in absorbent paper prior to placement in either plastic or paper bags to reduce respective pooling or seepage of fluid.

Other Medical Devices. These items should be packaged in the same manner as materials soiled with blood and blood products; however, when fluid seepage is not a problem, items may be discarded directly into plastic or paper bags without wrapping in absorbent material.

Liquids may be poured down a drain or in the toilet, for disposal in either the home septic system or the public sewer system. If indoor plumbing facilities are not available, these liquids should be placed in a leak- and break-resistant container that is tightly capped or stoppered, before placement in the household trash receptacle.

Recommended Storage and Disposal

Properly packaged household medical waste should be placed into home trash receptacles and made available for the next scheduled municipal or private trash pickup. If such pickup is unavailable, persons should transport the waste, as other household waste, to the sanitary landfill or municipal incinerator. Disposal of medical waste into the sewer system is addressed in Chapter 6.

Consistency With Other Household Medical Waste Guidance

Although existing guidance on management of home health care waste is limited, the Agency guidelines are comparable to recommendations provided by the Association for Practitioners in Infection Control (APIC).[15] The APIC recommendations address, among other things, proper home health care practices for primary protection of patients from disease and infection.

APIC recommends that needles be placed in capped puncture resistant containers and placed in trash receptacles when filled. APIC also recommends discharging body fluids to the toilet and placing soiled dressings, used gloves, and disposable equipment in plastic bags before discarding them. Other health care groups, such as the American Medical Association, have been contacted to assist in guidance development concerning this issue.

11.7 Alternative Management Options

EPA recommended guidelines for home health care waste provide a starting point for reducing potential risks posed by these wastes. However, the success of a voluntary program for managing household medical waste depends upon two major factors--ease of implementation and public willingness to participate. The Agency recognizes that some patients may show an unwillingness to participate and others may be unable to provide materials needed to safely package medical waste originating from home health care. For example, in cases where bedridden patients are totally dependent on others for care, food preparation may not occur in the patient's home. Thus, items such as disposable plastic jugs and containers needed for proper packaging of sharps may not be readily available in the home. Also, many poor and elderly patients may not have adequate supplies of plastic or paper bags for packaging of these wastes, or they may be unwilling to change current household waste management practices. Therefore, the Agency is seeking alternative or additional options for managing medical waste from home health care.

EPA is coordinating with suppliers of medical devices, pharmaceutical and home health care associations, and waste management associations to gather data on alternative disposal options for household medical waste which will reduce potential risks associated with improper disposal of these wastes. EPA is exploring the following options:

Option I

Some manufacturers and distributors of medical devices are providing sharps containers to certain home care patients.[16] Some of these companies provide pickup of filled containers; others instruct patients in proper disposal of the container. However, at this time, the Agency is not sure whether this service can be provided to all patients at a reasonable cost.

Option II

The National Solid Waste Management Association has suggested the use of pharmacies as home health care waste collection centers or drop-off points for sharps and other designated wastes. Under this approach, patients would return properly packaged used sharps and certain other medical devices to designated pharmacies. The pharmacy would bear the responsibility for proper storage and disposal of these wastes. This alternative to home disposal of sharps raises the following important issues which may discourage pharmacy participation in the program:

- increased risk of worker exposure from additional waste handling,
- limited storage areas,
- the need for uniform packaging of sharps (by patients) to facilitate pharmacy storage, and
- a shift in disposal costs from the household to the pharmacy.

The benefits derived from central collection centers may not outweigh the potential risks posed by increased handling and transportation of these wastes (i.e, motor vehicle transport from private homes to pharmacies) by individuals.

One variation on this option includes having individuals pay a deposit for the use of a rigid, puncture-resistant container, which they return to the pharmacy filled with used sharps, to receive their deposits back.[17]

Option III

The medical supply industry is also evaluating the use of prepaid disposal systems such as mail-back of used sharps and other medical devices. This option may have some utility in certain situations; however, it should be fully evaluated because of potential increased risks to workers and home health care workers or other persons who must repackage the waste materials for mailing. In addition, the Postal Service is considering limitations on certain shipments (see 54 FR 11970).

Option IV

Another option, although not an alternative to disposal with municipal refuse, involves manufacturer packaging of needles and syringes (and other sharps) in hard plastic packages that can be resealed or tightly capped for disposal. This approach is similar to the packaging used by certain razor blade manufacturers where the blade dispenser contains a compartment for used blades. A used sharp, once repackaged in its original rigid packaging, can be safely discarded into the household trash receptacle.

Option V

One final option is to encourage municipalities to conduct special programs for collection of these materials, which could be held, for example, in conjunction with a household toxics waste collection program. The household waste programs are typically conducted as an event when residents are encouraged to bring household chemicals to a central collection point, where the wastes are packaged and shipped to a hazardous waste facility. A potential drawback to this approach is the relatively infrequent scheduling of the events; with wastes that contain organic materials, some decay may occur. However, this approach may be valid for certain wastes that pose special concerns (for example, sharps).

Agency Action. EPA will evaluate the above listed options, and report progress in subsequent reports.

Exhibit 11-1.

HOME HEALTH CARE WASTE GUIDELINES

Educating Your Patients

Every year, Americans use over one billion sharp objects in their homes to administer health care. These "sharps" include lancets, needles, and syringes. If they are not disposed of in puncture-resistant containers, they can injure trash handlers, can increase the risk of infection if they come in contact with contaminated materials such as bandages, dressings, and surgical gloves, and can pollute the environment.

As health-care professionals, you plan an important role in instructing your patients and clients on how to safely practice health care at home. Through this brochure, we are asked your help in distributing the attached disposal tips to them. The tear-out explains how to safely dispose of sharps and other contaminated medical waste, such as bandages and soiled disposable sheets.

We urge you to distribute the disposal tips tear-out to your patients and to encourage them to read it. You might also place this information in areas easily accessible to all your patients and clients.

You can get additional free copies of this brochure or reprints of the tear-out by sending the attached order form to the EPA. For further information on medical waste, you can call the RCRA Hotline Monday through Friday, 8:30 a.m. to 7:30 p.m. EST. The national toll-free numer is (800) 424-9346; for the hearing impaired, it is TDD (800) 553-7672. In Washington, DC, the number is (202) 382-3000 or TDD (202) 475-9652.

Disposal Tips for Home Health-Care

You can help prevent injury, illness, and pollution by following some simple steps when you dispose of the sharp objectives and contaminated materials you use in administering health care in your home. You should place:

- Needles,
- Syringes,
- Lancets, and
- Other sharp objects

in a hard-plastic or metal container with a screw-on or tightly secured lid.

A coffee can will do, but you should be sure to reinforce the plastic lid with heavy-duty tape. Do not put sharp objects in any container that will be recycled or returned to a store. Do not use glass or clear plastic containers. Finally, make sure that you keep containers with sharp objects out of the reach of young children.

We also recommend that:

- soilded bandages,
- disposable sheets, and
- medical gloves

be placed in securely fastened plastic bags before you put them in the garbage can with your other trash.

Your state or community environmental programs may have other requirements or suggestions for disposing of your medical waste. You should contact them for any information you may need.

More Information

For additional free copies of these disposal tips, please call the RCRA Hotline Monday through Friday, 8:30 a.m. to 7:30 p.m. EST. The national toll-free number is (800) 424-9346; for the hearing impaired, it is TDD (800) 553-7672. In Washington, DC, the number is (202) 382-3000 or TDD (202) 475-9652.

Home Health-Care Sponsors

This program is sponsored by:

U.S. Environmental Protection Agency
American Diabetes Association
American Hospital Association
American Society for Hospital Engineering
American Society for Healthcare Environmental Services
Association for Practitioners in Infection Control
Association for State and Territorial Health Officials
Health Industry Distributors Association (HIDA)
Health Industry Manufacturers Association
National Association for Home Care
National Solid Wastes Management Association
Visiting Nurse Association

Exhibit 11-2.

HOME HEALTH CARE WASTE BROCHURE

An Important Message to Health Care Professionals

The Home Health-Care Program

Improper handling of wastes from home health-care activities may pose a risk of injury, infection, and environmental contamination. EPA and its co-sponsors have begun a program to educate recipients and providers of in-home health care.

The home health-care program focuses on the proper packaging and containment of needles, syringes, and other sharp objects before they are put into trash cans or other household receptacles. Each year, over one billion sharp objects are used in self-administered health care.

Because you--the health-care professional--play an important role in providing information and guidance to your patients and clients, EPA seeks your assistance in distributing the information provided in the attached flyer. The goal is to provide this information to every person who purchases or uses needles, syringes, or sharp objects in health-care activities in the home or who purchases any medication that is routinely administered by injection.

The flyer which makes up the last page of this brochure outlines simple procedures for disposing of household medical waste in a safe, environmentally sound manner. These procedures will reduce risks of injury, infection, and environmental pollution. Some general guidelines on proper disposal of other contaminated items such as bandages, dressings, soiled disposable sheets, and medical gloves are also included. We recommend that you place the flyers in areas easily accessible to all patients and clients.

The Federal Medical Waste Program

In response to incidents such as medical waste washing up on beaches, Congress enacted the **Medical Waste Tracking Act of 1988.** Under this law, EPA published regulations on March 24, 1989, setting up a demonstration program in several states to track medical wastes from where they are generated to where they are disposed. The regulations apply to medical practitioners and facility owners or operators who generate, transport, treat, or dispose of certain medical wastes.

Home health-care waste has been excluded from the **Medical Waste Tracking Act,** and therefore such wastes are not regulated. Even though home health-care wastes are excluded from the law, Congress has requested EPA to investigate whether these wastes contribute to health or environmental problems and to evaluate the need for alternative guidelines for handling these wastes.

Based on the outcome of the study, Congress may require additional regulation of household waste. While the study continues, EPA believes it is prudent to begin a nonregulatory, educational approach to handling waste from home health-care activities.

How Home Health-Care Providers Can Help

You can help by informing your patients about safe disposal methods. For example, sharp objects (such as lancets or syringes with needles) that are not placed in puncture-resistant containers can cause physical injury, increase the risk of infection if associated with infectious materials, and contaminate the environment. The debris found on New York beaches contained a small proportion (approximately one percent) of syringes, blood vials, and other medical materials. This debris appears to have resulted from improper waste-management practices such as littering by individuals or during bulk waste transfer operations. The extent to which home health-care wastes are part of this problem is not known. However, syringes and other sharp objects placed in household trash can be released to the environment during waste handling and transfer operations and pose a physical hazard to handlers and anyone else who comes in contact with them.

EPA, along with its co-sponsors, have established guidelines to ensure the proper containment of such materials before they leave the home and become part of the waste stream. We urge you to participate in this education program by distributing the flyer and encouraging your patients and clients to read it.

For further information on medical waste, please call the RCRA Hotline Monday through Friday, 8:30 a.m. to 7:30 p.m. EST. The national toll-free number is (800) 424-9346; for the hearing impaired, TDD (800) 553-7672. In Washington, D.C., the number is (202) 382-3000, or TDD (202) 475-9652. For additional free copies of this brochure or reprints of the flyers, please complete and mail the attached order form or call the RCRA Hotline.

Office of Solid Waste
United States
Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

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CHAPTER 12

MEDICAL WASTE REUSE, RECYCLING AND REDUCTION

Section 11008(a)(12) of RCRA requests information on "available and potentially available methods for the reuse or reduction of the volume of medical waste generated." Chapters 6 and 7 addressed some of the available methods for reducing the volume of medical wastes that have been generated. This chapter briefly describes some of the possible source reduction strategies to reduce, avoid, or eliminate a waste's generation, as well as possible recycling and reuse techniques.

12.1 Recycling and Reuse

Potential recycling and reuse techniques generally fall into two types: recycling techniques that involve substantial reprocessing in ways that usually affect the waste's structural integrity, and techniques that involve a cleaning/disinfection process and subsequent reuse (without significantly affecting the waste's structural integrity). An example of the former technique is the recycling of glassware by remelting and forming into glass again; an example of the latter is the cleaning, sanitizing, and sterilization of a disposable or reusable medical device.

The various recyclable materials of a medical facility's wastestream that can be reprocessed by remanufacturing include glassware, paper, metals, and plastics. EPA is aware of one facility that recycles laboratory glassware by returning it to a glass recycling facility[1]. Plastics may also be recycled by melting and reextrusion; for plastic medical wastes, this technique may be feasible in some situations[2]. At this time EPA has no information on the number of facilities recycling paper, or metal-containing medical wastes. In future reports, EPA will address the extent of recycling and the feasibility of these techniques in greater detail.

Use of medical supplies is widely practiced for certain items. For instance, laboratory glassware is frequently cleaned and sterilized for reuse, and bed linens are laundered for reuse.

Reprocessing or reuse of single-use medical devices raises a number of technical, economic, ethical, and legal issues. The presence of residues from the reprocessing could affect the quality of a patient's care; the health care facility may be concerned about potential liability from reusing the device; devices that were not designed for multiple uses could fail when reused, and there may be inadequate or non-existent quality control for the sterilization procedures used[3].

12.2 Source Reduction

Health care facilities may have a number of options available for avoiding, reducing or eliminating a medical waste's generation. If some wastes are generated due to overpurchasing items with a limited shelf life, or due to storage or handling practices that cause materials to be less useful, improvements in these materials management practices can potentially yield reductions in wastes generated. Instituting procedures for employee suggestions and developing employee training and "waste awareness" are other possible methods.

EPA intends to conduct a more in-depth review of facility's equipment and supply use practices which may reveal other waste reduction possibilities. For example, it may be possible to modify the design of medical equipment so that less waste is generated. Materials substitutions may be evaluated in the final report for waste reduction potential. EPA intends to investigate these ideas and report on them in future reports to Congress.

12.3 Generation Rates

Medical facilities can evaluate their waste management practices using indicators of waste quantity and composition. Chapter 1 discusses the amounts of medical wastes generated (although that analysis is limited to regulated medical wastes). A large medical waste generator, such as a hospital, can assess its own waste generation rates according to the different waste sources in the facility. For example, one study found that an important variable in hospital waste generation rates is the total paid staff of a unit, for a 24-hour period, excluding doctors[4]. Table 12-1 lists the correlations found; although the data may not reflect current waste generation rates, they illustrate one technique in which a hospital could systematically identify large waste sources.

Table 12-1.
Medical Waste Production, by Source

SOURCE	GENERATION RATE (lb/day)
Heavy-care units (surgery, burns, maternity)	4.47 times the number of paid staff for those units
Light-care units (psychiatric, neurology)	2.77 times the number of paid staff for those units
X-ray, emergency room, central supply	0.48 times the number of patients treated
Laboratory and clinics	0.19 times the number of tests or patients

12.4 Agency Action

In future reports, EPA will evaluate the potential for recycling the various components of the medical wastestream, and the extent to which facilities already use recycling techniques. In addition, EPA will attempt to assess the potential reduction in single-use/disposable medical supplies, while considering the reasons that have caused health care facilities to increase their use.

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